AD-A259 068

1	2	1
	0	

AD_____

REPORT NO T10-92

VALIDATION OF TWO TEMPERATURE PILL TELEMETRY SYSTEMS IN HUMANS DURING MODERATE AND STRENUOUS EXERCISE

October 1992

U S ARMY RESEARCH INSTITUTE OF ENVIRONMENTAL MEDICINE

Natick, Massachusetts

20030225055





UNITED STATES ARMY
MEDICAL RESEARCH & DEVELOPMENT COMMAND

Ž. 1

DISCLAIMER

The views, opinions and/or findings in this report are those of the authors, and should not be construed as an official Department of the Army position, policy or decision, unless so designated by other official documentation.

Human volunteers participated in these studies after giving their free and informed consent. The investigators adhered to the policies for protection of human volunteers as prescribed in AR 70-25 and USAMRDC Regulation 70-25 on Use of Volunteers in Research.

Citations of commercial organizations and trade names in this report do not constitute an official Department of the Army endorsement or approval of the products or services of these organizations.

DTIC AVAILABILITY NOTICE

Qualified requesters may obtain copies of this report from Commander, Defense Technical Information Center (DTIC) (formerly DDC), Cameron Station, Alexandria, Virginia 22314.

Approved for public release; distribution is unlimited.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to everage 1 hour per reporting, including the time for reviewing instructions, searching existing data sources, gethering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Washington meadquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Direct Maintains Supplied Advision No. 2, 2222, 2422, 2421 to the Officer of Management Resident, Proprinciple Resident, Propr

Davis Highway, Suite 1204, Arlington, VA 22202-4302			
1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE October 1992	3. REPORT TYPE A Technical	ND DATES COVERED Report
A TITLE AND SUBTITLE Validation of Two Tempers Humans during Moderate as 6 AUTHOR(5) Lou A. Stephenson, Mark I Deborah A. Toyota and Mar	d Strenuous Exerci-		S. FUNDING NUMBERS
7. PERFORMING ORGANIZATION NAME US Army Research Institut Kansas Street Natick, MA 01760-5007		Medicine	8. PERFORMING ORGANIZATION REPORT NUMBER
9. SPONSORING/MONITORING AGENCY Same as Block 7.	NAME(S) AND ADDRESS(ES)		10. SPONSORING, MONITORING AGENCY REPORT NUMBER
11. SUPPLEMENTARY NOTES			
12a. Distribution/Availability stat Approved for public relea		unlimited.	12b. DISTRIBUTION CODE
			_L

13. ABSTRACT (Maximum 200 words)

This study examined how two core temperature telemetry pill systems (Konigsberg Instruments, KI (T_w) and Human Technologies, HTI (T_w)) compared to esophageal temperature (T_w) and rectal temperature (T_w) during exercise/rest cycles. T_w (17.8±8.1 min), T_w (17.8±8.4 min) and T_w (22.5±9.9 min) were at steady state faster during moderate exercise (p≤0.001) than T_w (35.7±5.3 min). The change in core temperature par time (slope) was greater for T_w (0.073±0.037°C•min¹) than T_w (0.039±0.023°C•min¹) and T_w (0.018±0.005°C•min¹) and T_w (0.049±0.029°C•min¹) was greater than T_w. The total change in core temperature was larger (p≤0.01) for T_w (0.93±0.21°C) and T_w (0.90±0.24°C) than T_w (0.63±0.25°C). The change in T_w was not different from T_w (0.76±0.25°C). T_w did not respond as fast as T_w and did not measure large changes in core temperature like T_w or T_w. T_w was more responsive than T_w and T_w responded like T_w. The concept of using a temperature sensor in a pill as a clinical thermometer is good, but mobility of the pill makes it less suitable as a research tool than esophageal or rectal temperature measurements.

14. SUBJECT TERMS Temperature Regulation	15. NUMBER OF PAGES 76					
	•	16. PRICE CODE 136				
17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT			

TECHNICAL REPORT NO. T10-92

VALIDATION OF TWO TEMPERATURE PILL TELEMETRY SYSTEMS IN HUMANS DURING MODERATE AND STRENUOUS EXERCISE

by

Lou A. Stephenson, Mark D. Quigley, Laurie A. Blanchard Deborah A. Toyota and Margaret A. Kolka

October 1992

U.S. Army Research Institute of Environmental Medicine Natick, Massachusetts 01760-5007

DTIC QUALITY PRESENCED 2

Addabasom For	i
721S 82/41	Ď
974C #48	ō
((MANAGOR) 4 and	C
Jastification	
Ry	ويينيوستاكيون ، اسم
Distribution/	
Aveilability C:	
Avail and/	or
Dist Special	
1.1	
1	

CONTENTS

List of Figures	• • •		• •	• •	• •	• •	•	• •	•	• •	•	• •	•	•	• •	•	•	• •	•	•	•	• •	•	•	•		٠	•	iv	
List of Tables .	• • •	• • •	• •			•	•		•		•		• •	•		•	•		•	•	•		•	•	•		•		vi	
Foreword			• •			•	•		•		•	• •		•	• •	•	•		•	•	•		•	•	•		•	•	vii	
Acknowledgem	ents			••	• •	•	•	• •	•	٠.	•		•	•		•	•		•	• •	•		•	•	•		•	•	viii	
Executive Sum	mary	• •	• •				•	٠.	•		•		•	•		•	•		•	•	•	• •	•	•	•		•	•	1	
Introduction		• • •	•			•	•		•	• •	•			•		•	•		•	•	•		•	•	•		•	•	3	
Methods			• •		• •	•		••	•	• •		• •		•		•	•		•	•	•	, • •	•	•	•		•	•	7	
Results and Dis	scuss	ion	•		• •		•		•		. •			•		•	•	• •	•	•	•		•	•	•		•		14	ļ
Conclusions	• • • •			• •	• •		•		•	• •	. •	• •		•		•	•		•	•	•		•	•	•		•	•	56	ļ
Recommendation	ons		• • •		• •				•		•	• •		•		•	•		•	•	•		•	•	•		•	•	57	r
References		• • •	• •	• •	• •		•		•	• •		• •		•		•	•		•	•	•		•	•	•	• •	•	•	58	ļ
Appendix		• • .	• •		• •	•	•	• • ·	•	• •	•	• •		•		•			•	•	•		•	•	•	• •	•	•	61	į
Distribution List							_		_										_										72)

LIST OF FIGURES

Figure 1:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer A.
Figure 2:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer B.
Figure 3:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer C.
Figure 4:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer D.
Figure 5:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer E.
Figure 6:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer F.
Figure 7:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer G.
Figure 8:	Core Temperature and Heart Rate Responses During Rest and Bouts of Moderate and Heavy Intensity Exercise for Volunteer H.
Figure 9:	Correlation Coefficients for KI Pills Ingested by Volunteers A and B.
Figure 10:	Correlation Coefficients for KI Pills Ingested by Volunteers C and D.
Figure 11:	Correlation Coefficients for KI Pills Ingested by Volunteers E and F.
Figure 12:	Correlation Coefficients for KI Pill Ingested by Volunteer G.

- Figure 13: Correlation Coefficients for HTI Pills Ingested by Volunteers A and B.
- Figure 14: Correlation Coefficients for HTI Pills Ingested by Volunteers C and D.
- Figure 15: Correlation Coefficients for HTI Pills Ingested by Volunteers E and F.
- Figure 16: Correlation Coefficients for HTI Pills Ingested by Volunteers G and H.
- Figure 17: Hysteresis Seen During Calibration of KI Pills Ingested by Volunteers A and B.

LIST OF TABLES

- Table 1: Test Volunteer Characteristics.
- Table 2: Protocol Variation Between Individual Volunteers.
- Table 3: Individual Core Temperatures (°C) and Time Observed (min).
- Table 4: Change in Core Temperature (°C) Indices With Activity State Changes.
- Table 5: Time (min) to Observe 0.1°C Change in Core Temperature Indices With Activity State Changes.
- Table 6: Individual Slopes and Intercepts from Linear Regression Equations.

 Generated from Observed Temperature as a Function of Time.
- Table 7: Change in Core Temperature (°C) from Rest Temperature to Peak Temperature.
- Table 8: Telemetry Pill Identification and Calibration Correlation Coefficients for Esophageal and Rectal Temperatures (Appendix).

FOREWORD

The Joint Working Group of the Physiological and Psychological Effects of the NBC Environment and Sustained Operations on Systems in Combat (P²NBC²) identified a need for a temperature telemetry system which accurately measured core temperature in soldiers involved in P²NBC² studies in the field. The temperature telemetry system had to be precise enough to be used as a clinical index of core temperature to reduce the risk of heat injury in volunteers participating in field studies. In order to routinely use temperature telemetry during field tests, the telemetry systems used were compared with esophageal and rectal temperature in a laboratory test described in this report. Two telemetry systems were tested; one made through a collaborative effort of Walter Reed Army Institute of Research (WRAIR) and P²NBC² based on a contract with the developer, Konigsberg Instruments, Inc. (Pasadena, CA), and the other made by Human Technologies, Inc. (CorTemp™; St. Petersburg, FL). Both systems included an ingestible temperature sensor/pill, a receiver, and a data storage system. Each system was expected to reliably measure and store core temperature data from individual soldiers involved in lengthy field studies.

ACKNOWLEDGEMENTS

The authors are indebted to the volunteers who performed in these experiments. We gratefully acknowledge the technical support provided by Ms. P. Burgoon, Mr. B. Cadarette, Ms. L. Levine, SGT W. Latzka, Ms. D. Cohen, Ms. A. Tarentino, and Ms. G. Carrubba. We also thank the medical monitors, CPT J. Cook, MAJ M. Reardon and LTC W. Curtis.

Both temperature telemetry systems were supplied by COL Redmond, Chief, Special Studies Branch, Department of Behavioral Psychology, WRAIR, in support of the funding agency, P2NBC2. COL Redmond also advised us in the use of the telemetry systems, in particular the KI system, as did MAJ J. Leu and SSG P. Gutierrez (Special Studies Branch, WRAIR). We also thank SSG Gutierrez for quickly providing USARIEM with additional supplies as needed during the study.

Funding for this study was provided, in part, by the Joint Working Group of the Physiological and Psychological Effects of the NBC Environment and Sustained Operations on Systems in Combat (P²NBC²) program of the U.S. Army Chemical School.

EXECUTIVE SUMMARY

This study examined how two core temperature telemetry pill systems (Konigsberg instruments, KI (Tw) and Human Technologies. HTI (Tw)) compared to esophageal temperature (T_) and rectal temperature (T_) during exercise/rest cycles. Two hours after swallowing both pills, eight volunteers exercised on a cycle ergometer (T,=29°C, T_a= 11°C) for 40 min at 40% peak Vo₂, rested 15 min, then completed 3 cycles of 5 min of exercise at 80% peak Vo, and 5 min of rest. T., T., T., and T., were recorded every 30 s. T. (17.8±8.1 min), T. (17.8±8.4 min) and T. (22.5±9.9 min) were judged to be at steady state faster during moderate exercise (p≤0.001) than T_a (35.7±5.3 min). The change in T, with change in activity (rest/exercise/recovery) was significantly less than the change in T_m, T_m and T_m (p≤0.001). However, the mean change in core temperature during steady-state moderate exercise was not significantly different (p=0.12) among the four core temperature indices. The change in core temperature per time (slope) was greater for T_m (0.073±0.037°C•min⁻¹) than T_m (0.039±0.023°C•min⁻¹) and T_{*} (0.018±0.005°C•min⁻¹). In addition, this slope was greater for T_w (0.049±0.029°C•min⁻¹) than T_w. However, the T_w slopes were not different from T, slopes. The total change in core temperature (peak - rest) was larger (p≤0.01) for T_{∞} (0.93±0.21°C) and T_{∞} (0.90±0.24°C) than T_{ω} (0.63±0.25°C). The change in T_u was not different from T_u (0.76±0.25°C). The majority of the T_u data indicates that it does not respond as fast as T., but responds just as quickly as T., T_u, during a 1.0°C change in core temperature lagged by nearly 0.4°C. Therefore, T_u did not measure large changes in core temperature as effectively as T_ or T_ The HTI pill detected the total change in core temperature better than the KI pill (p≤0.01). Overall, T_m tracked dynamic changes in core temperature significantly faster than T_m, although T_{m} did not track dynamic changes as well or as consistently as T_{m} . T_{m} was an effective index of the total change in core temperature (~1°C) during the experiment. T_m was a more responsive index of core temperature than T_m, and T_m responded like T... Finally, T. tracked core temperature more quickly than the telemetry pills did, and T_M and T_M showed a faster response to changing core temperature than did T. The concept of using a temperature sensor in a pill may be useful clinically, but mobility of the pill makes this temperature measurement less suitable for research than esophageal or rectal temperature measurements.

INTRODUCTION

Thermoregulatory strain occurs in soldiers during field and laboratory tests of military equipment and systems. In laboratory tests, either rectal or esophageal temperature of the volunteers is monitored to ensure that internal body temperature (core temperature) does not exceed safe clinical limits. Each of these core temperature indices is reproducible and not biased by environmental temperature (2,8,14); however, the slow response time of rectal temperature is well known (7,8,11,15,16). Esophageal temperature measurements are not used in the field, but are routinely used in laboratory tests which are concerned with the study of thermoregulation. Rectal temperature measurements are used as a index of core temperature in the field and in some types of laboratory studies of exercise and heat stress responses. In the field, it is not always practical to monitor core temperature because volunteers reject the use of rectal probes as a clinical thermometer or the current portable system requires that a medical observer be close to the volunteer at all times. This methodology interferes with field exercises and requires large numbers of medical observers. For example, a medical observer would effectively disrupt the military mission of a tank crew while he monitors the core temperature of each crew member. A solution to monitoring core temperature during field exercises would be to monitor core temperature at an accepted internal site and to transmit the core temperatura responses some distance from the told using telemetry. In this way, the medical observer could communicate to the crew or individual when core temperature limits have been exceeded. Alternatively, the individual could carry a temperature telemetry data logger that contained an alarm which would be activated if a core temperature safety limit were exceeded during the field exercise.

STATEMENT OF PURPOSE

The purpose of this study was to compare how well two different temperature telemetry systems tracked rapid and absolute changes in core temperature compared with esophageal and rectal temperatures during exercise. The temperature telemetry systems tested were 1) a prototype using the lingestible temperature sensor/transmitter daveloped by Konigsberg Instruments, Inc. (Pasadena, CA) under the supervision of COL Redmond, WRAIR [as part of the Chemical Defense User Safety System

(CDUSS; 19), the Biomedical Safety Monitoring System (BSMS; 19) and the Biomedical Field Monitoring System (BFMS; 18)], and 2) the CorTemp™ ingestible temperature sensor and data logger (HTI; Human Technologies, Inc., St. Petersburg, FL). Specific questions investigated were:

- 1. Are rapid changes in core temperature measured as accurately by the temperature telemetry systems as they are by esophageal temperature?
- 2. How does core temperature measured by the temperature telemetry systems compare to rectal temperature during rapid changes in core temperature?
- 3. How effectively do the temperature telemetry systems measure absolute changes in core temperature?

Esophageal measurements were included as the "gold standard" for comparison purposes. Rectal temperature measurements were included because they are often used as the core temperature index for field studies. It was hoped that the temperature telemetry pills would be as reproducible as esophageal and rectal temperature measurements, but could also demonstrate faster responses than rectal temperature measurements.

BACKGROUND

The Joint Working Group of the Physiological and Psychological Effects of the NBC Environment and Sustained Operations on Systems in Combat (P²NBC²) identified a need for the development of a temperature telemetry system which accurately measured core temperature in soldiers involved in P²NBC² studies in the field. The development of radio telemetry systems which measure body temperature has been outlined recently by Redmond et al. (19). Mackay, who was involved in the development of radio telemetry of physiological data, described the principles of that technology in detail (13). In an attempt to validate temperature telemetry, which has been routinely used during field tests, those telemetry systems were compared to esophageal and rectal temperature measurements in a laboratory test. The first system was designed to operate from within armored vehicles and over considerable

distance [this system (KI) was developed through a collaborative effort of Walter Reed Army Institute of Research (WRAIR) and P²NBC² (12, 19) by Konigsberg Instruments, Inc.]. The second telemetry system tested was a commercially available system marketed by Human Technologies, Inc. (CorTemp™; St. Petersburg, FL) developed at the Applied Physics Laboratory of Johns Hopkins University. Both systems included an ingestible temperature sensor/pill, a receiver, and a data storage system and were expected to reliably measure and store core temperature data from individual soldiers involved in field studies.

Before telemetry systems for monitoring core temperature can be judged as an appropriate replacement for other indices of core temperature, they must be compared to those measures of core temperature which are currently accepted as accurate by thermal physiologists and clinicians. Brengelmann (2) reviewed the criteria required for an accurate and reliable measure of core temperature as cited by earlier investigators (7, 8, 20). The measurement must accurately reflect the hypothalamic temperature because the hypothalamus is the site of the thermoregulatory controller. The site where core temperature is measured must also respond rapidly and accurately to changes in brain temperature and must not be influenced by environmental temperature changes. This is particularly important because rapid heat gain and loss by individuals in field studies must be measured so that heat injury to participants in field studies can be prevented. Finally, the measurement should be reliable, easy to use in the field and harmless to the test volunteer.

The first of these criteria, that the measured temperature reflect brain temperature, has been addressed by several investigators (1, 2, 7, 22, 23). In 1951, Eichna et al. (7) reasoned that the temperature of blood in the left ventricle would be the best approximation of what they called "critical deep tissue" temperature. They equated critical deep tissue temperature with the temperature of the central thermoreceptors in the brain (7). Historically, the U. S. Army Research Institute of Environmental Medicine (USARIEM) and other research groups have used rectal temperature as an equilibrated or "steady state" index of internal body temperature. Elanna et al. (7) noted that rectal temperature was not a satisfactory index of internal temperature because changes in T_{re} occurred after changes had already occurred in heat loss or heat production effectors during body heating or cooling. These investigators (7)

concluded that the use of rectal temperature as an index of deep body temperature was appropriate during "steady state" conditions. Both oral and esophageal temperature responded rapidly enough to changes in body temperature to be used as an index of brain temperature (8). Furthermore, there was a highly significant relationship between heat elimination and oral temperature, which Gerbrandy et al. (8) interpreted as evidence that oral and esophageal temperature reflect the temperature at the central thermoreceptors. Esophageal temperature is the best method of tracking blood temperature in the right heart, and consequently, it responds very quickly to dynamic changes in deep body temperature (2,8,20,22,23).

Tympanic or auditory meatus temperature has also been used by some groups as an index of internal body temperature in laboratory studies (1, 9, 21-23). Initially tympanic temperature was used because it responded similarly to brain temperature in the monkey and the cat (1). It has been proposed that tympanic temperature is the best core temperature index in humans because it more accurately reflects hypothalamic temperature and would also account for selective brain cooling (3,5,6), but the existence of selective brain cooling in humans has not been proven and remains highly controversial (5, 17, 25). In fact, Jessen and Kuhnen (10) have since reported evidence against selective brain stem cooling in humans. The interpeak latencies for evoked brain stem potentials, which depend on brain stem temperature, did not change during face fanning in hyperthermic humans. Also, esophageal temperature did not change significantly during face fanning while tympanic temperature decreased slightly and forehead temperature decreased significantly (10). The main detraction for using tympanic temperature is that it more reliably tracks skin temperature than core temperature in humans (9, 21, 22). This bias makes tympanic temperature an unreliable index of brain temperature (23), while esophageal temperature effectively tracks brain temperature. The disagreement among researchers is in part due to the effective insulation around the tympanic thermocouple. In animal experiments, the tympanic thermocouple was carefully insulated and implanted (1), techniques not possible in humans. Brinnel and Cabanac (3) presented evidence that tympanic temperature tracks escephageal temperature if the tympanic thermocouple is situated on the lower anterior quarter of the tympanic membrane and properly insulated from the rest of the ear canal. This technique is risky in that the tympanic membrane might be punctured when the thermocuaple is

placed against it. However, Shiraki et al. presented data from a human case study which showed that tympanic temperature did not track brain temperature as did esophageal temperature (23).

The current study was designed to use changes in activity state (rest-exercise-recovery-heavy exercise-recovery) to force many changes in core temperature during the experiment. Esophageal temperature was used as the most rapidly responding index of hypothalamic temperature in this study.

METHODS

VOLUNTEERS

Eight males volunteered to serve as test subjects after they were informed of the purpose, procedures, and known risks of this study. Each signed a consent form describing the study which was approved by the USARIEM Human Use Review Committee and the Surgeon General's Human Use Review Office. Each volunteer was given a medical examination and granted medical clearance before participating in the study. Investigators adhered to guidelines established for research on humans in USARIEM M 40-68, AR 70-25 and USAMRDC 70-25 Use of Volunteers in Research. The physical characteristics of the volunteers are described in Table 1.

PEAK AEROBIC POWER TEST

Peak aerobic power (peak Vo₂) was determined for each volunteer during exercise on a cycle ergometer which was modified so that the volunteer pedalled the ergometer as he sat in a chair attached behind the ergometer (Table 1). The procedure began with a five min warm-up period during which the volunteer exercised at a work intensity that elicited a heart rate of approximately 125 beats per min. After a few minutes rest, peak aerobic power was determined (Sensormedics 2900) during continuous resistance work. The work load was increased approximately 30 W every two min until the volunteer could no longer continue pedalling at 60 revolutions per min or when he voluntarily quit pedalling. Peak Vo₂ was designated when oxygen

Table 1
Test Volunteer Characteristics

Volunteer	Height	Weight	Age	Ao	Peak Vo₂
	(cm)	(kg)	(years)	(m²)	(ml·kg ⁻¹ ·min ⁻¹)
A	183	72	23	1.9	50
В	178	82	19	2.0	41
C	163	72	19	1.8	45
D	185	76	19	2.0	47
E	173	80	18	1.9	47
F	170	65	20	1.8	53
G	180	93	19	2.1	45
Н	186	97	19	2.2	36
MEAN	177	80	20	2.0	46
SD	8	11	2	0.1	5

uptake did not change more than 150 ml with increased ergometer resistance. Individual peak $\dot{V}O_2$ was used to calculate the relative work intensity for each experiment.

EQUIPMENT/INSTRUMENTS

The four methods of measuring core temperature included rectal temperature (T_m) , esophageal temperature (T₋), CorTemp™ (Human Technologies, Inc., St. Petersburg, FL) ingestible temperature sensor (HTI, Tw) and the ingestible temperature sensor developed by Konigsberg Instruments, Inc. (Pasadena, CA) under the supervision of COL Redmond, WRAIR, as part of CDUSS, BSMS and BFMS (KI, T₄). Rectal temperature was measured at a depth of 10 cm past the anal sphincter in the rectum using an YSI thermistor (Yellow Springs, OH). The J-type thermistor was calibrated in a water bath prior to use. Esophageal temperature was measured at a predetermined location in the esophagus deemed the "hot spot". The "hot spot" was located by systematically determining temperature in the esophagus beginning at approximately 25% of each volunteer's height until the temperature was at a peak presumably due to the anatomical proximity to the great vessels of the heart. Once the site of peak temperature in the esophagus was found, the T, probe was marked and was inserted to this depth. In order to eliminate the cooling of the T probe, volunteers did not swallow saliva during these experiments. Esophageal temperature was measured using a 28-gauge copper-constantan thermocouple encased in PE-200 polyethylene tubing (Clay-Adams) which was sealed at one end with dental epoxy. This probe was calibrated in a water bath prior to use. Both the thermocouple and thermistor data were collected using a programmable volt meter (Hewlett-Packard 3497A) and stored on floppy disks by a computer (Hewlett-Packard 9816).

The CorTemp[™] telemetry system included an ingestible temperature sensor (2 cm by 1.3 cm in diameter), FM antenna and data recorder system. In this system, temperature modifies a continuous, low-frequency radio wave (19). The temperature sensor included a silver oxide battery (1.5 V) which provided the power for sensing and transmitting temperature. The components of the sensors were encapsulated in epoxy and covered with silicone rubber. Temperature was transmitted through the body to a double bandoleer-type antenna and recorded by a data logger. A 9 V

alkaline battery (Radio Shack) provided power sufficient for data collection for four hours while temperature was measured every 30 s.

The CDUSS system used was described in a report to the U.S. Navy (12). Rather than continuous radio wave transmission, this system encodes temperature data by pulse interval modulation of the bursts of low power radio waves in the FM Band which are characteristic for each transmitter (19). For this study, the KI system was used in a prototype configuration of software and hardware which included the temperature telemetry transmitter (T2D), receiver (TR6B) and antenna communicating directly with a computer (Zenith Supersport or Zenith portable 286) by an RS232 interface. The temperature transmitter (~2.5 cm by 1.5 cm in diameter) included a 1.5 V silver oxide battery, two circuit boards and an antenna embedded in epoxy and coated with silicone rubber. The coating of the temperature transmitter was a material approved previously by the FDA. The components used in the TR6B receiver included a transceiver, a microreceiver controller, two I/O boards and a power supply which were contained in an aluminum case. DC power was supplied to the power supply board by your lithium batteries (1.5 V each). The TR6B locked on radio frequency transmission from the T2D as picked up by an antenna wrapped around the volunteer. Redmond et al. documented the performance of the CDUSS system (19) which used different software than the KI system used in this study. They reported that pill temperature correlated well with oil bath temperature when the oil temperature was measured as it cooled from 40°C to 36°C.

Calibration

All calibrations were performed by biomedical engineers in the Biophysics and Biomedical Modelling Division and Thermal Physiology and Medicine Division, USARIEM. Rectal thermistors and esophageal thermocouples were calibrated prior to use to ensure that temperature measurement in body temperature range was accurate to the standards of the National Bureau of Standards (NBS). HTI pills were calibrated in a water bath to a NBS thermometer for a range of temperatures between 36 and 39°C. Only those pills that were highly correlated (correlation coefficient > 0.98) to the NBS thermometer were used in the study (Appendix). Seven of the 19 HTI pills calibrated were not used because they were not highly correlated to NBS temperature.

The KI pills were calibrated in a stirred water bath to a range of temperatures between 36 and 39.5°C (Appendix). There were many problems in calibrating these pills, the most severe being inability to collect data using the prototype BSMS system during calibration. Calibration was attempted on 36 KI pills, but a signal could be detected consistently during the calibration procedure in only 11 KI pills. These problems were documented in depth in correspondence to COL Redmond (USARIEM Memoranda SGRD-UE-UEZ (70) dated 3 JUL 1990 and SGRD-UE-MEP (70) dated 26 SEP 1990) and included 1) the use of the temperature pills beyond their shelf life, 2) significant interference of the FM bands used in the 88-92 MHz frequency by commercial radio stations in the Boston area, and 3) software problems in the data acquisition program. These problems limited the number of KI pills available for the laboratory test, therefore reducing the number of volunteers in which the KI pills were tested. Also, calibration problems prevented the exclusion of KI pills which did not correlate with water bath temperature.

PROTOCOL

Two volunteers were studied each test day, although the exercise test times were staggered so that one volunteer at a time could be studied during exercise. The first volunteer arrived at the laboratory at 0700 h and the second volunteer arrived at 0900 h. Upon arrival at the laboratory the volunteer swallowed both telemetry pills with water. He then ate a light breakfast consisting of two pieces of toast with about 200 ml of juice. After breakfast, the volunteer inserted the rectal and esophageal temperature probes. Two (±0.5) hours after swallowing the pills the volunteer was taken to the environmental test chamber to complete the exercise experiment.

Experimental Procedures and Environmental Conditions

The ambient temperature in the environmental test chamber was $29.5 \pm 0.6^{\circ}$ C and the dew point temperature was $11.4 \pm 1.0^{\circ}$ C. Upon entering the test chamber the volunteer was weighed and the antennae for the telemetry systems were attached to his torso. He then sat in a chair which was positioned behind the cycle ergometer while all other instruments were attached. T_{∞} , T_{∞} , T_{∞} , and T_{∞} were measured every 30 s throughout the experiment. Heart rate was measured at 5 min intervals by

electrocardiography. A 15 min rest period preceded exercise.

After rest the volunteer exercised for 40 min at 40% peak Vo. When T. stabilized during moderate exercise, the volunteer drank 100 ml of water so that it could be determined whether the HTI and KI pills were still in the stomach. Volunteers A and B were given drinks at ~15 and 30 min of exercise, but the remaining six volunteers drank only once, at ~20 min of exercise.

Following moderate exercise there was another 15 min rest period. To test whether the telemetry systems accurately tracked rapid changes in core temperature, there were three cycles of intense exercise (80% peak $\dot{V}O_2$) for 5 min interspersed with 5 min rest periods. During intense exercise, heart rate was measured every minute.

After the experiment, the volunteers lived in a laboratory which served as a dormitory until it could be verified that the telemetry pills had passed through their digestive tracts. In those cases in which the signal was not detected periodically, the stools of the volunteer were collected until the pills were identified. The length of time it took for passage of the pills through the digestive system of each volunteer is shown in Table 2.

Data Analysis

The tracking responses of the four indices of core temperature are subjectively described to assess how suitable T_M and T_M were for detecting the rapid changes in core temperature elicited by exercise or recovery. There were several other approaches used to ascertain differences in tracking characteristics, as well as steady-state responses among the core temperature indices. First, the steady-state temperatures during rest and moderate exercise, and peak temperature during heavy exercise were tabulated along with the time it took to reach these values (Table 3). Second, the change in core temperature for each activity level was calculated. The magnitude of the change was constrained to the period of exercise or recovery as shown in Table 4. In addition, the time it took for each core temperature index to increase or decrease 0.1°C in response to activity changes was compiled for each individual experiment (Table 5). In order to compare tracking responses of the four

Table 2
Protocol Variation Between Individual Volunteers

Volunteer	Time After Ingestion When Volunteer in Test Chamber (h:min)	Experiment Duration (min)	KI Pill Passage Time (h)	HTI Pill Passage Time (h)
A	1:00 - 2:40	95 ¹	47.5	31.5
. В	2:00 - 3:40	100	25	44.5
C	2:15 - 3:43	88²	12.5	31.5
D	2:00 - 3:40	100	7	29.5
Ε	2:00 - 3:40	100	28	.28
F	3:00 - 4:40	100	12.5	12.5
G	2:00 - 3:40	100	8	30
H	2:30 - 4:10	100	_3	36

¹Volunteer A ate breakfast before arriving at the laboratory. During exercise he experienced what appeared to be gastric reflux into the esophagus from his description of "heartburn" and what was observed in the T_e data. Testing was halted at 95 min by the investigator due to volunteer discomfort. For all other volunteers the protocol was modified to that described above so that a light breakfast was eaten immediately after pill ingestion. None of the other volunteers experienc ad "heartburn".

²Volunteer C had severe muscular cramping in the gluteus maximus during the first intense exercise bout so the experiment was terminated when the cramping persisted after eight min of rest.

³Volunteer H did not ingest a KI pill because a signal could not consistently be detected from any of the KI pills available at the time of calibration for this experiment.

indices of core temperature to changes in heat production and dissipation due to the exercise/rest cycle of the experiment, regression equations were generated from the temperature changes as a function of time during both increasing and decreasing temperatures. The slopes (Table 6) of the individual regression equations were compared by analysis of variance with repeated measures. T, T, and T, were compared to T_a during those times when all data were available, in this case, when core temperature was increasing during exercise and in five volunteers. Because we were able to collect more temperature data from the HTI system than the KI system, we were able to compare those data more extensively with T, and T. As described in the DISCUSSION the experimental protocol differed for Volunteers A and C, and there were no Tu data for Volunteers G and H, therefore, all the analyses could not be done for all volunteers and all core temperature indices. As many volunteers and data as possible were used in the analyses of variance with repeated measures which determined differences among the indices of core temperature. When significant differences were identified by analysis of variance (p<0.05), Tukey's test of critical differences was used for post hoc comparison.

RESULTS AND DISCUSSION

All data on human test subjects were collected in the spring of 1990 (April - June).

The prototype KI telemetry system was used in only seven of the eight experiments because only nine of 36 KI pills were suitably calibrated and responsive prior to consumption by the volunteer as discussed in the METHODS. Two of these pills were used in other experiments. For Volunteer C, the T_N data were so sporadic after ingestion that T_N was useless as a core temperature index during exercise. Although Volunteer G ingested a KI pill, the signal could not be detected at all after ingestion. The data for the seven KI pills used in this study are presented in the Appendix (Figures 9-12). The bench calibrations done in this study indicated that the KI sensor, as a thermometer, was not as accurate as reported when the calibration was done using an oil bath which was allowed to cool from 40°C to 36°C (<0.05°C; (19)). Seven of nineteen HTI pills, for which a water bath calibration was attempted, were eliminated because of either too much fluctuation around calibrated water bath

temperature or difficult signal detection. Four HTI pills were used in another study and two HTI pills were calibrated during preliminary tests of the HTI telemetry system. The calibration data for the HTI pills used in the current study are presented in the Appendix (Figures 13-16).

Figure 1 shows the core temperatures and heart rate responses for Volunteer A. The experimental protocol was different for this volunteer than the others (Table 2) because he experienced what he described as "heart burn" and what appeared to be gastric reflux as indicated from the T_ data (Figure 1). This volunteer swallowed the pills without eating a light moal. The heart rate response in Figure 1 demonstrates the changes in exercise intensity during the experiment. After 16 min of rest, Volunteer A began exercising at a moderate intensity (40% peak Vo.). Approximately 100 ml of water (room temperature) was ingested at mins 34 and 52 which corresponded to 18 and 36 min of moderate exercise. These times can be identified in Figure 1 by the dramatic decrease in T as water cooled the esophageal probe. The quick recovery of T_w from cooling is also apparent. Both T_w and T_w show the decrease in temperature due to drinking water which indicated that both pills were in the stomach. The bsolute temperature and the time at which each index was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. Moderate exercise ended at 56 min and the change in core temperature is shown in Table 4. These data were compiled from the time when each core temperature index was judged to have reached a steady state temperature. The T data collection was temporarily interrupted due to a malfunction of the thermocouple connector during the recovery from moderate exercise until approximately minute 70, so T data were collected only for the last minute of the 15 min recovery period. Ta decreased by 75% and T_m decreased by 68% during that period. During this recovery period, T_m decreased more than it had increased during exercise (Tables 4 and 5). This might be due to the KI pill moving in the gastrointestinal (GI) tract during the 55 min of moderate exercise and recovery, or to the response characteristics of this particular KI pill to change in temperature (Appendix). T, decreased only slightly during this recovery period (Table 4). Heavy exercise (80% peak Vo₂) began at minute 71. Table 4 shows the change in the core temperature indices at the end of the 5 min work period. T_e increased by 0.8°C, but the other core temperature indices changed less dramatically during the time of heavy exercise. Additionally, Figure 1 shows that

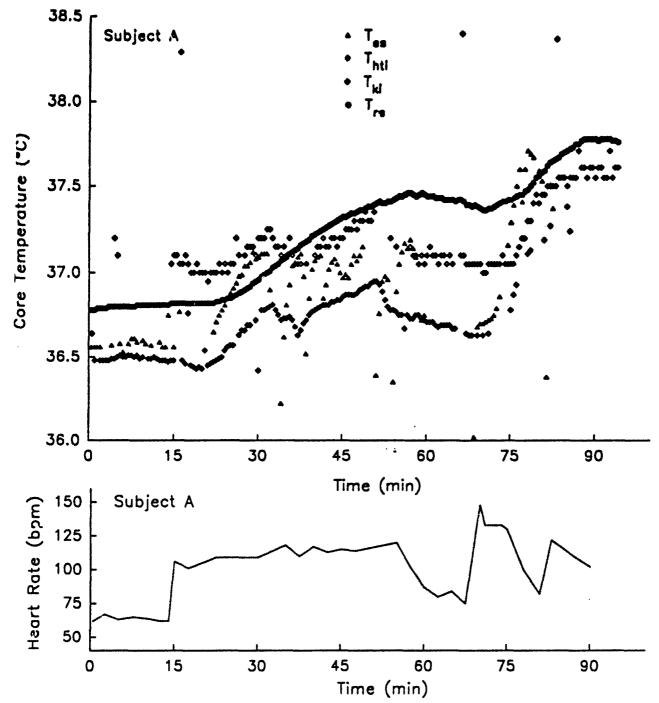


Figure 1 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

after exercise stopped at 76 min, while T_m continued to increase for another 90 s, T_m T_m and T_m continued to increase longer during recovery, when those indices finally reached a peak value. T_m responded much more rapidly to the change in core temperature during heavy exercise and recovery from heavy exercise than did the other three core temperature indices in this experiment. The volunteer's indigestion and technical difficulties that occurred with the T_m thermocouple did not obscure the more rapid response of T_m to change in core temperature than the other three core temperature indices.

The experimental protocol was standard for Volunteer B (Table 2) as reflected in the core temperature and heart rate responses (Figure 2). During rest, T_m decreased by 0.4°C although both T_w and T_n data indicate that Volunteer B was close to thermal aguilibrium at this time. In this case it appears that the HTI pill moved in the GI tract from a hot location, perhaps adjacent to the liver, to a cooler location. A change in temperature of that magnitude is comparable to the change that occurs during moderate exercise (Table 4) and highlights the argument that pill mobility could easily undermine research which uses temperature pill telemetry as an index of core temperature. Had the pill moved when moderate exercise began (minute 15) the increase in core temperature might have been missed. The brief plateau in T_m at minute 17 through minute 19 might be due to pill movement. The T_k data appear to indicate that the KI pill also moved in the GI tract during rest, although these data are more scattered than the T_M data. Approximately 100 ml of water (room temperature) was ingested at mins 30 and 45 which corresponded to 15 and 30 min of moderate exercise (Figure 2). T. decreased both times when Volunteer B drank water, but T. cooled only after the second drink. Tu may have decreased after both drinks but it is hard to determine that with any degree of certainty because of the variability in that measure (Figure 2). Apparently, the pills were in the GI tract at some point beyond the stomach as it took a greater volume of water (two drinks) to effect a temperature change than was observed for Volunteer A. The absolute temperature and the time at which each index was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. Moderate exercise ended at 55 min and the change in core temperature is shown in Table 4. During recovery from moderate exercise, T_ responded quickly and decreased by nearly the same degree as it increased during moderate exercise (Table 4). Both the Tu and Tu data, although

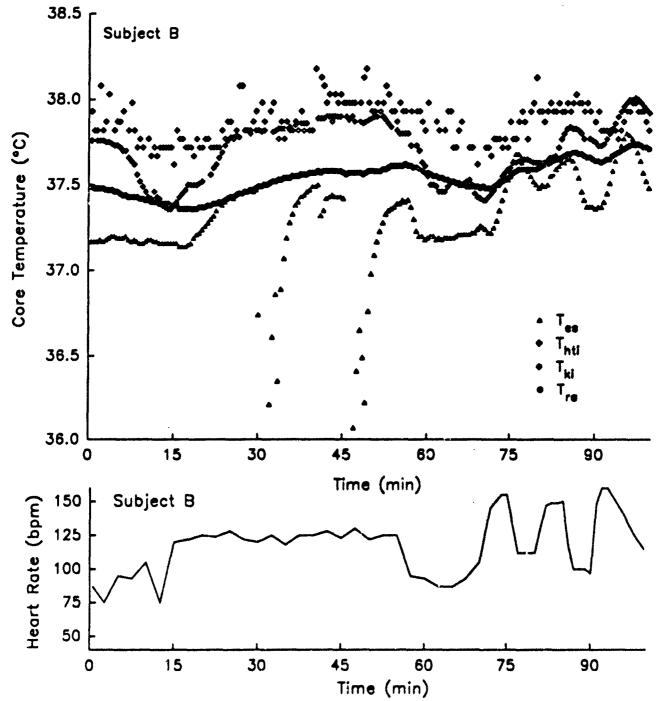


Figure 2 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

not as rapidly responding as T_m also decreased during recovery by almost the same magnitude as they increased during moderate exercise. T_m decreased by 50% of the initial increase during this recovery period (Table 4). The heavy exercise (80% peak Vo₂) work/recovery cycles began at minute 70. Figure 2 shows that both T_m and T_m responded quickly to the change in work, and to some extent parallel the change in heart rate. Both T_m and T_m have a damped response to the heavy work and recovery during the first two cycles, although T_m responds more like T_m during the third cycle. The T_m response is still damped during the final cycle of heavy work and recovery. For this experiment, T_m responded much more rapidly to the change in core temperature during the moderate exercise bout than the other three indices of core temperature, but during the heavy exercise and recovery cycles both T_m and T_m responded quickly. Perhaps, during the last 30 min of the experiment the HTI pill did not move in the GI tract. The T_m data could indicate that this pill did move in the GI tract because it became more responsive during the last heavy exercise/recovery cycle.

The experimental protocol was modified for Volunteer C (Table 2) so that he only performed one cycle of heavy work and recovery from that work (Figure 3). During rest, some T_u data were collected and used in Tables 4 and 5, but during exercise only sporadic readings were made (Figure 3). T_ increased rapidly during moderate work and T_m and T_m data indicated that those core temperature indices lagged behind T_ T_ decreased abruptly when Volunteer C drank 100 ml of water (room temperature) at 38.5 min which corresponded to 23.5 min of moderate exercise (Figure 3). T_u did not respond to this drink. The absolute temperature and the time at which each index was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. Moderate exercise ended at 55 min and the change in core temperature is shown in Table 4. During recovery from moderate exercise, T_m responded quickly and decreased by about 70% of the increase in T_a during the moderate exercise (Table 4). T_m had a slower response time than T,, but returned to pre-exercise level. T, decreased only slightly during this rocovery period (Figure 3, Table 4). The one heavy exercise (80% peak VO₂) work/recovery cycle began at minute 70. Figure 5 shows that both T_m and T_m responded quickly to the change in core temperature due to work. T_ does not increase during heavy exercise mainly because at 5 min of heavy exercise it is still

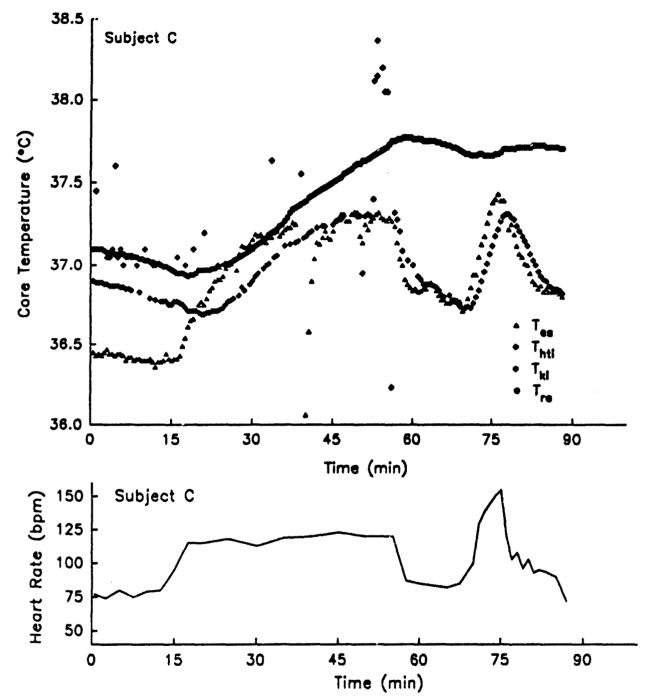


Figure 3 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

decreasing in response to the previous recovery period. Five minute of recovery from heavy work was not long enough for T_n to reflect the increased heat stored during the exercise session.

Volunteer D performed the standard experimental protocol (Table 2) and the core temperature and heart rate responses are shown (Figure 4). During rest, all four indices of core temperature are fairly stable and by the beginning of moderate exercise Volunteer D was in thermal equilibrium. During moderate exercise Volunteer D drank 100 ml of water (room temperature) at 30 min which corresponded to 15 min of work (Figure 4). T_ and T_ decreased transiently after the drink. The data indicate that the HTI pill, but not the KI pill, was in the stomach or upper small intestine. The absolute temperature and the time at which each index was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. The changes in all indices of core temperature are shown in Table 4. During recovery from moderate exercise, T responded more quickly than the other three indices (Figure 4). T_s, T_{ss} and T_{ss} although not as rapidly responding as T_{ss}, also decreased to some extent during recovery (Table 4). The heavy exercise/recovery cycles began at minute 70. Figure 4 shows that both T_m and T_m responded quickly to the increase in core temperature caused by exercise. During recovery and subsequent work/recovery cycles T responded quickly to change in core temperature. T was blunted during the last two heavy exercise recovery cycles. Both T, and T, were damped compared to the T_a response to the heavy work and recovery during all cycles of heavy work and recovery. In this experiment, T responded much more rapidly to the change in core temperature during the moderate exercise bout than the other three indices of core temperature. During the first heavy exercise and recovery cycle both T, and T, responded quickly. However, during the last 2 cycles of heavy exercise and recovery the T_m response was more like T_m and T_m than T_m. The change in T_m response characteristics might indicate that the HTI pill was moving through the GI tract during the experiment.

Volunteer E also performed the standard experimental protocol (Table 2). The core temperature and heart rate responses are presented in Figure 5. During rest, the indices of core temperature are fairly stable by the last 5 min before moderate exercise. Volunteer E drank 100 ml of water (room temperature) at 40 min which

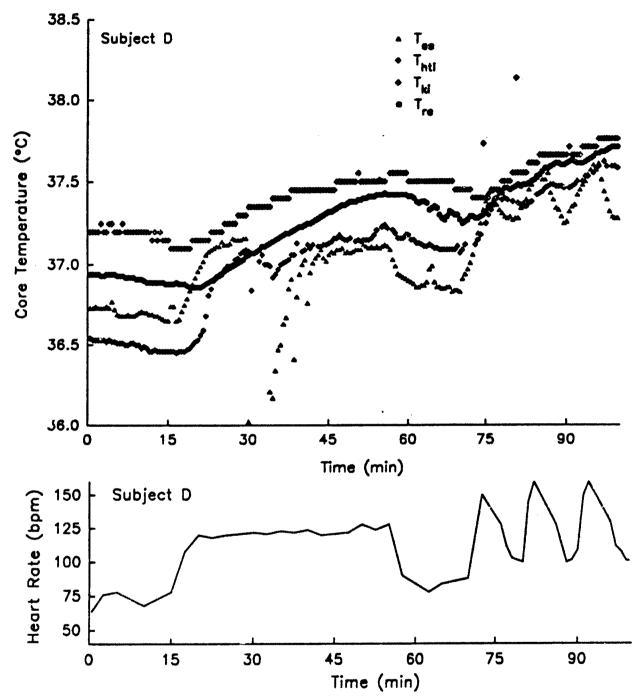


Figure 4 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

corresponded to 20 min of work (Figure 5). T., T., and T., decreased transiently after the drink, indicating that both the HTI and KI pills were in the stomach. The absolute temperature and the time at which each index was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. The changes in all indices of core temperature are shown in Table 4. During moderate exercise, T, T, and T, responded more quickly than T, (Figure 5). However, during recovery from moderate exercise T_m and T_m responded less quickly than T_m, but more quickly than T_m (Figure 5, Table 4). When the heavy exercise/recovery cycles began, both T_m and T_m responded quickly to the initial work, while T_m lagged behind those two indices. During recovery and subsequent work/recovery cycles T_ continued to respond quickly to change in core temperature, while both T_k and T_k responses were blunted during the last two heavy exercise recovery cycles. Both Tu and Tu were much more dynamic in response than T in this experiment. Both the KI and HTI pills were presumably located in the stomach or upper small intestine during this experiment and showed a more dynamic response to changing core temperature than the experiments in which the pill changed only slightly, if at all, when water was consumed (Volunteers B, D, and H; Figures 2, 4, and 8).

The core temperature and heart rate responses (Figure 6) to the standard experimental protocol (Table 2) for Volunteer F are shown. Volunteer F was in thermal equilibrium prior to moderate exercise (Figure 6). At the beginning of moderate exercise, there is a transient decrease in T, and T, and perhaps in T, and T_a, before core temperature increases as heat production increases. This phenomenon at the onset of exercise is due to shunting of cooler blood from the skin to the core caused, presumably, by transient catecholamine vasoconstrictor action on cutaneous blood vessels. The absolute temperature and the time at which each index was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. The changes in all indices of core temperature are shown in Table 4. During moderate exercise, T. and T. responded more quickly than T. and T_u responded faster than T_n (Figure 6). When Volunteer F drank 100 ml of water at 40 min, which corresponded to 25 min of work, T., T., and T., decreased transiently which indicated that the HTI and KI pills were in the stomach. During recovery from moderate exercise, T, decreased sooner than T, and T, but the two pill temperatures responded much faster than T, (Figure 6, Table 4). During the heavy

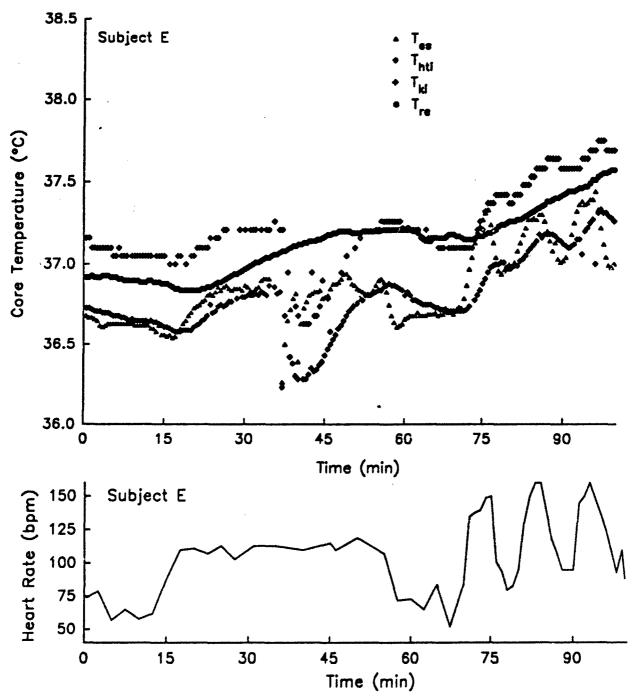


Figure 5 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

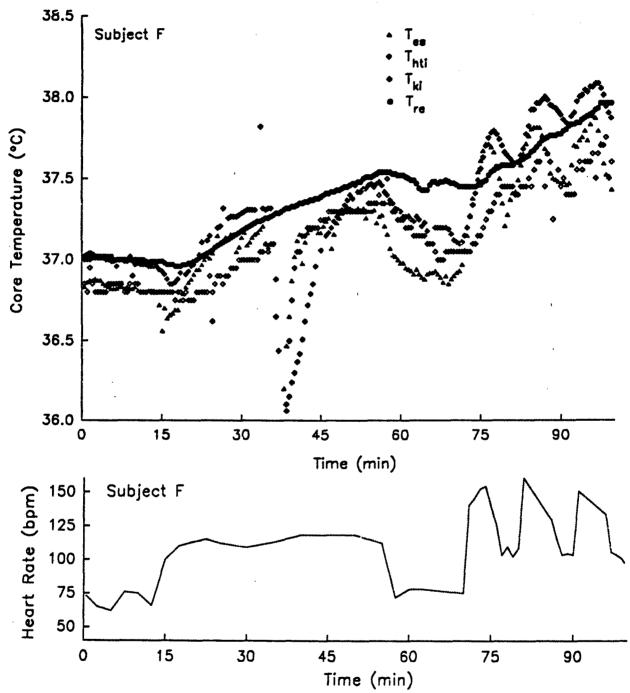


Figure 6 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

exercise/recovery cycles, both T_m and T_m responded quickly to the initial work, while T_m lagged behind those two indices. During recovery and subsequent work/recovery cycles, T_m continued to respond quickly to changes in core temperature, while responses of both T_m and T_m were somewhat blunted during the last two heavy exercise recovery cycles. Both T_m and T_m were again more responsive than T_m in this experiment. This experiment is another example which shows that when both the KI and HTI pills were presumably located in the stomach, they exhibited a more dynamic response to changing core temperature than those experiments in which the pill temperature changed only slightly, if at all, when water was consumed (Volunteers B, D, and H; Figures 2, 4, and 8). The difference in the responses of the pill temperatures between the two types of experiments is apparently due to the location of the pills in the GI tract.

The core temperature and heart rate responses (Figure 7) to the standard experimental protocol (Table 2) for Volunteer G are shown. Tu was not measured in this experiment due to the inability of the data acquisition system to detect the KI pill signa'. Volunteer G was in thermal equilibrium prior to moderate exercise (Figure 7). The absolute temperature and the time at which each index was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. The changes in the three indices of core temperature are shown in Table 4. During moderate exercise, T, responded more quickly than T, and T, (Figure 7). The sluggish response of T_m during moderate exercise was different than observed in the other experiments. The HTI pill might have been in the volunteer's stomach in water (200 ml) which was swallowed before the experiment when he placed the esophageal probe. Perhaps the water was absorbed more slowly from the stomach of Volunteer G than from the other volunteers' stomachs so that water remained in the stomach ~1 h after being consumed. Otherwise, the response characteristics of this HTI pill were different during the first twenty min of moderate exercise in this volunteer than the other pills. When Volunteer G drank water at minute 40, T. decreased transiently while T_m decreased for about 10 min, then it increased fairly rapidly toward the end of moderate exercise. The sluggish response of T_m to the drink of water is consistent with the HTI pill being in water in the stomach. During recovery from moderate exercise T_m decreased sooner than T_m, but the T_m response was more dynamic than its earlier responses, and was much faster than T, (Figure 7, Table 4). During the

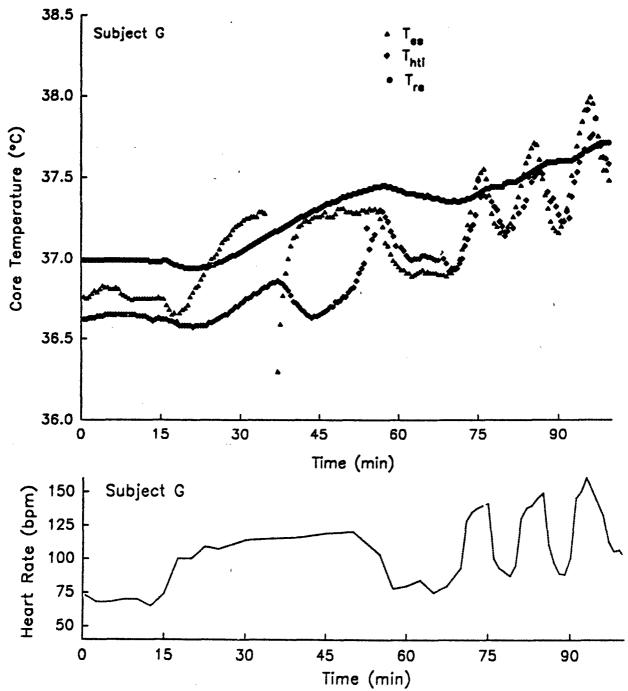


Figure 7 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

heavy exercise/recovery cycles, both T_m and T_m responded quickly and similarly to all changes in core temperature. The response of the HTI pill during heavy exercise/recovery cycles was different than during moderate exercise and was the most like T_m of any experiment. T_m responses during the heavy work/recovery cycles were not dynamic enough to detect the change in core temperature during recovery, but did measure an overall increase during the cycles. This experiment showed a problem with using T_m when the HTI pill was presumably located in the stomach because it responded sluggishly during moderate exercise and when water was consumed. However, for some reason, perhaps absorption of water in the stomach or movement of the pill out of the stomach, the response of T_m was greatly improved during the heavy work/recovery cycles.

The core temperature and heart rate responses (Figure 8) to the standard experimental protocol (Table 2) for Volunteer H are shown. For reasons cited in the METHODS, T_N was not measured in this experiment. By the end of the rest period the three indices of core temperature were stable (Figure 8). The time at which each index of core temperature was judged to have reached steady state are shown for rest, moderate exercise, and heavy exercise in Table 3. Core temperature changes are shown in Table 4. During the whole experiment, T_m responded as dynamically as seen in all other experiments. In this experiment, T_m and T_m responded in near synchrony (Figure 8). The sluggish response of T_m during this experiment was another variation of response description for the HTI pill. An explanation of its response is that it was in a location in the GI tract which was more thermally insulated than observed in other experiments. For example, the HTI pill might have been in the large intestine. This assumption would explain why T_m characteristics were so similar to T_m characteristics.

Although much information can be derived from the above description of T_M and T_M during each individual experiment, only intuitive conclusions can be drawn from the individual experiments. Intuitive conclusions alone are important as decisions can be made about the usefulness of a pill temperature sensor in measuring core temperature, however by analyzing the common features of the individual experiments more statistically powerful conclusions can be drawn. There were several approaches used to ascertain differences in response time among the core temperature indices.

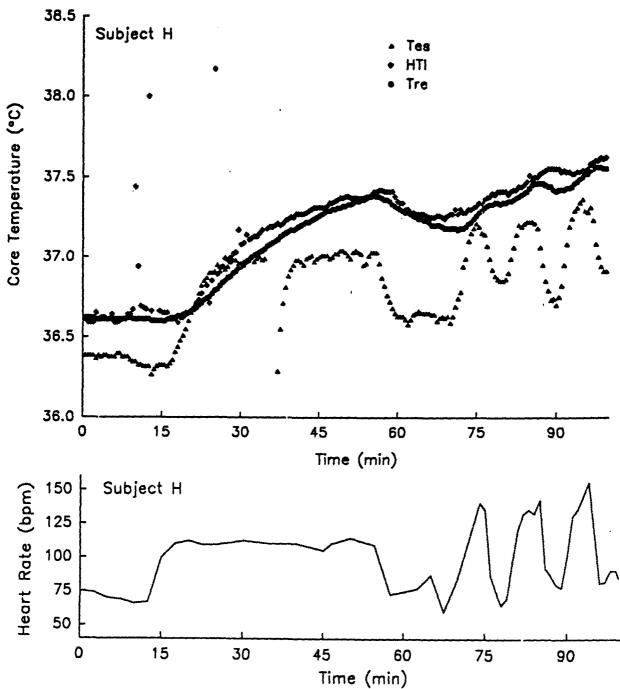


Figure 8 Core temperature and heart rate responses during rest and bouts of moderate and heavy intensity exercise.

First, the steady-state core temperatures during rest and moderate exercise, and the peak core temperature during heavy exercise, along with the time it took to reach these core temperatures were tabulated (Table 3). Second, the change in core temperature for each activity level was calculated. The magnitude of the change was constrained to the period of exercise or recovery as shown in Table 4. The change in core temperature during steady-state moderate exercise was examined alone because that condition in the experiment would be analogous to those field exercises in which service members would be exercising at a moderate work pace, in themal equilibrium. In addition, the time it took for each core temperature index to increase or decrease 0.1°C in response to a change in activity was compiled for each individual experiment (Table 5) and the slope of each increase or decrease in core temperature was calculated when possible (Table 6). Finally, the total change in core temperature during the experiment (peak - rest) was calculated (Table 7) to determine whether large changes in core temperature could be measured effectively with the two telemetry pills.

The two-way analyses of variance with repeated measures indicated a significant main effect of activity state, as changes in activity state were used to force changes in core temperature. In general, the analyses indicated significant interaction between the core temperature indices and the activity states. Neither the significant main effect of activity state nor the significant interaction between core temperature indices and activity will be discussed further as each was an expected result of the experimental design of the study. The entire focus of the data analyses was on the comparisons of the core temperature indices.

The intent of the study was to compare $T_{\tt m}$ and $T_{\tt m}$ to two accepted indices of core temperature ($T_{\tt m}$ and $T_{\tt m}$). Because the experimental protocol differed for Volunteers A and C, and there were no $T_{\tt m}$ data for Volunteers G and H, and limited $T_{\tt m}$ data for Volunteer C, not all analyses could be done for all volunteers and all core temperature indices. However, by limiting the volunteer number to five, as well as by limiting the activity states, analysis of variance with repeated measures were done to compare all four core temperature indices (Tables 3-6). To fully present the remaining data, and to examine the relationship of $T_{\tt m}$ with $T_{\tt m}$ and $T_{\tt m}$ in greater detail than could be done with $T_{\tt m}$ data, as many volunteers ($n \ge 6$) as possible were used in the data analyses

A CANTAL CONTROL OF A CANTAL C

to compare T., T., and T.,

The equilibrated core temperature during rest (Table 3) was different among the four indices (n=6). T_{∞} averaged 36.70(±0.3)°C which was significantly less (p≤0.01) than T_{∞} (37.14±0.3)°C and T_{∞} (36.99±0.2°C), but not different from T_{∞} (36.78±0.3°C). T_{∞} was also significantly greater (p≤0.01) than T_{∞} . When only three indices (T_{∞} , T_{∞} and T_{∞}) were compared using all eight volunteers (Table 3), both T_{∞} (36.66±0.3°C) and T_{∞} (36.75±0.3°C) were significantly lower (p≤0.01) than T_{∞} (36.94±0.2).

When the four core temperature indices were compared during moderate steady state exercise (Table 3; n=5) there were no significant differences among indices (p=0.06). However, when the analysis was limited to T_{ee} T_m and T_m and included all eight volunteers, T_{ee} (37.18±0.2°C) and T_m (37.20±0.3°C) were lower (p≤0.01) than T_m (37.46±0.2°C). This confirms the report of Sparling *et al.* (24) that T_m is lower than T_m during rest and exercise, aithough the difference between the two indices averaged between approximately 0.4-0.8°C in that study. The differences between T_m and T_m in the current study were much less than that report (24) and may indicate the merit of giving the volunteers a light meal after ingesting the HTI pill and waiting 2 h before initiation of exercise.

Trie peak temperatures (when obviously not aberrant points, as seen in many of the core temperature figures, and not constrained to a specific activity state) measured during the experiment were not different among the four indices (n=5; p=0.65) or among $T_{\rm sec}$ $T_{\rm ne}$ and $T_{\rm ne}$ (n=8; p=0.61). That is, the differences previously observed for equilibrated temperatures during rest and moderate exercise were no longer apparent. This observation is noteworthy because it indicates both the magnitude of the variation among individuals in the change in core temperature with activity state changes (Table 4) and the slow response time of $T_{\rm e}$ and $T_{\rm e}$ (Table 3).

The time it took for each of the four core temperature indices to reach steady state during moderate exercise (Table 3) was also compared using a one-way analysis of variance with repeated measures (n=5). T_∞ (17.8±8.1 min), T_∞ (17.8±8.4 min) and T_∞ (22.5±9.9 min) were judged to be at steady state faster during moderate exercise (p≤0.001) than T_∞ (35.7±5.3 min). When all eight volunteers were used in the analysis

Table 3 Individual Core Temperatures (°C) and Time Observed (min)

Steady-State Rest	T _u T _u T _u T _u T _u T _u	37.10 36.48 36.81 13-15 15 12.5-15 12-14.5	37.38 12.5-15 12.5-14.5 14-15	36.98	36.88 14-15 14-15 11.5-15			- 36.62 36.96 10-14 - 13-15 13-15	- 36.66 36.60 11.5-12.5 - 14.5 13-15
Steach-Sta		36.48	37.36	36.77	36.46	36.65	36.96		
	Volunteer T. T	A 36.56 37	B 37.16 37	C 36.39 37	D 36.65 37	E 36.62 37	F 36.81 36	G 36.75	Н 36.32

Table 3 (cont.) Individual Core Temperatures ("C) and Time Observed (min)

Steady-State Moderate Exercise (40% Peak vo.)

		26.0 41.5						
	i	26.5						
Ļ!	30.5	27.5	46.5	27	33.5	ಕ	33.5	2.5
۲,	37.44	37.46 38.08 37.79 37.58	37.71	37.42	37.20	37.51	37.43	37 38
۲ <u>ء</u>	36.85	37.79	37.30	37.18	36.62	37.32	36.86	27 27
۲,	37.25	38.08	•	37.50	37.21	37.10	•	(
F.	37.11	37.46	37.31	37.16	36.91	37.21	37.29	27.00
Volunteer	<	8	ပ	G	Ш	u.	g	3

Table 3 (cont.) Individual Core Temperatures (°C) and Time Observed (min.)

_
Z
Ø
Pig
Š
eak Vo,
Peak Vo.
0% Peak Vo.

Ļ.	88	26	82.5	98.5	66	97.5	88	97.5
ب ے	88	4	77.5	4	4	96.5	44	98.5
قبر	87	96.5	•	8	96.5	98.5	•	•
μ!	78	8	92	8	8	8	8	88
۳,	37.78	37.74	37.72	37.71	37.57	37.96	37.99 - 37.86 37.71	37.58
72	37.38	38.01	37.31	37.62	37.33	38.08	37.86	37.62
۳	37.71	38.98	•	37.78	37.75	37.75	•	ŧ
H _a	37.71	37.79	37.43	37.61	37.44	37.88	37.99	37.36
Volunteer	<	80	ပ	a	w	L	9	I

to compare T_{ex}, T_{to} and T_{ex}, the time it took T_{ex} (37.17±1.58 min) to reach steady state temperature was greater (p≤0.001) than T_{ex} (17.75±2.19 min) and T_{ex} (25.06±3.17 min). In this analysis, T_{ex} was at steady state before T_{ex} (p≤0.001). When the time it took to reach peak core temperature for heavy exercise was compared among the four indices (n=5), there were no significant differences found (p=0.06) when changes were not confined to a specific activity state. Yet, when only T_{ex}, T_{ex}, and T_{ex} were compared (n=8; p≤0.01), T_{ex} peaked earlier (91.1±8.7 min) than T_{ex} (94.8±6.1 min). Peak T_{ex} (93.2±7.7) was not different from either T_{ex} or T_{ex} (Table 3).

There were significant differences among changes in core temperature with change in activity state (Table 4). The analysis (n = 5; Volunteers A, B, D, E, F) comparing all four indices of core temperature by change in activity state (rest \rightarrow 40% peak \forall 0; 40% peak Vo, → recovery; recovery → 80% peak Vo,) indicated that the change in T, was significantly less than the change in T_m, T_m and T_m (p≤0.001). When the number of volunteers was reduced by one (Volunteer A) to include all the changes in activity state for the experiments (Table 4), the analysis indicated that the change in T_ was greater than the other three core temperature indices (p≤0.001). When only T_m T_m and T_m were compared (n = 7; Volunteers B-H) for the first four changes in activity state (Table 4), th∋ change in T_∞ was greater than T_∞ (p≤0.05) and T_∞ (p≤0.001) and the change T_∞ was greater than the change in T_∞ (p≤0.01). When Volunteer C was eliminated from the analysis, which allowed comparisons of more activity states with the three indices of core temperature, the change in T, was greater than T, and T, (p≤0.001). The statistical analyses for the change in the core temperature indices with change in activity state, in general, confirm the descriptive analyses for the individual experiments. That is, T tracked core temperature more quickly than the telemetry pills did, and $T_{\text{\tiny M}}$ and $T_{\text{\tiny M}}$ showed a greater response to changing core temperature than did T_.

In order to examine the portion of the experiment which was most like a field exercise during which the soldiers would be exercising at a moderate pace for a long enough time to be in steady-state, the change in core temperature for the four indices of core temperature were compared during steady-state moderate exercise (n=5; Table 4). The mean change in core temperature as measured by T_{∞} (0.41±0.12°C), T_{ω} (0.26±0.10°C), T_{ω} (0.43±0.19°C), and T_{∞} (0.44±0.19°C) was not significantly

Table 4
Change in Core Temperature Indices (°C) With Activity State Changes

Rest → 40% Peak Vo.

Volunteer	T.,	T _w	T _m	T,
A	0.55	0.15	0.47	0.63
В	0.30	0.36	0.43	0.20
C	0.92	•	0.53	0.73
D	0.51	0.35	0.70	0.54
E	0.29	0.16	0.17	0.31
F	0.40	0.30	0.36	0.52
G	0.54	•	0.24	0.45
н	0.58	• ,	0.71	0.78

40% Peak Vo, → Recovery

Volunteer	T _{ee}	T _N	T _{to}	T,
Α	-0.41	-0.25	-0.32	-0.08
В	-0.28	-0.36	-0.33	-0.10
C	-0.60	•	-0.58	-0.03
D	-0.33	-C.05	-0.09	-0.15
E	-0.30	-0.11	-0.11	0.01
F	-0.33	-0.10	-0.20	-0.08
G	-0.40	•	0.13	-0.07
н	-0.42	•	· -0.13	-0.20

Table 4 (cont.)

Change in Core Temperature Indices (°C) with Activity State Changes

Recovery → 80% Peak Vo₂ (1)

Volunteer	T _{ee}	T _u	T _M	Τ,,
Α	0.80	0.10	0.30	0.08
B	0.40	0.15	0.14	0.07
C	0.67	•	0.38	-0.02
D	0.55	-0.05	0.18	0.05
E	0.66	0.11	0.16	-0.04
F	0.79	0.15	0.44	0.05
G	0.61	•	0.39	0.15
Н	0.63	•	0.08	0.08

80% Peak Vo_z (1) → Recovery

Volunteer	T.,	T _w	T _M	T,	
A	*	•	•	4	E ***
В	-0.10	0.06	0.03	0.05	
C	-0.31	•	0.09	0.05	
D	-0.11	0.15	0.13	0.14	•
E	-0.33	0.16	0.10	0.09	
F	-0.46	0.30	0.10	0.10	
G	-0.37	•	-0.24	0.06	
Н	-0.36	•	0.07	0.08	

Table 4 (cont.)
Change in Core Temperature Indices (°C) with Activity State Changes

Recovery → 80% Peak Vo. (2)

Volunteer	T.,	T _u	T _M	Т.,
A	•	•	•	*
В	0.17	0.05	0.20	0.09
C	•	•	•	•
D	0.27	0.11	0.05	0.08
E	0.33	0.21	0.16	0.07
, F	0.60	0.10	0.28	0.09
G	0.51	•	0.33	0.07
н	0.37	•	0.10	0.09

80% Peak $\dot{V}O_{2}$ (2) \rightarrow Recovery

Volunteer	T.,	T _M	T _m	Т.,	
Α	4	•	•	•	
В	-0.29	-0.11	-0.08	0.04	
C	•	•	•	•	
D	-0.29	0.0	0.03	0.07	
E	-0.25	0.0	-0.02	0.09	
F	-0.34	-0.10	-0.03	0.10	
G	-0.52	•	-0.20	0.07	
н	-0.52	. •	0.04	-0.01	

Table 4 (cont.)

Change in Core Temperature Indices (°C) with Activity State Changes

Recovery → 80% Peak Vo. (3)

		o., / 00/01 0u.	, , , ,	
Volunteer	T.,	Tu	T _M	T,
A	•	4	•	•
В	0.41	0.0	0.21	0.07
C	•	•	•	•
D	0.35	0.05	0.09	0.04
E	0.37	0.11	0.13	0.07
F	0.32	0.15	0.14	0.11
G	0.75	•	0.40	0.06
Н	0.66	•	-0.01	0.08
	80% P	eak Vo₂ (3) → R	ecovery	
Volunteer	т	Т.,	т.	т

Volunteer	T.,	T _u	T _M	T _m
A	•	•	•	•
В	-0.34	-0.05	-0.06	0.0
С	•	•	•	•
D	-0.32	0.05	0.03	0.06
E	-0.39	0.0	0.01	0.08
F	-0.36	-0.10	-0.16	0.08
G	-0.43	•	-0.09	0.05
Н	-0.45	•	0.08	0.05

different (p=0.12). Also, when the change in $T_{\rm ex}$, $T_{\rm ini}$, and $T_{\rm ini}$ during moderate exercise only were compared (n=8; Table 4), there was no difference among those indices (p=0.48). During moderate exercise, and when the volunteers were in thermal equilibrium, a similar change in core temperature was measured by each of the four indices.

The time of an observable change in core temperature (0.1°C) with a change in activity state (Table 5; n=4) was faster (p \leq 0.001) for T_{∞} (2.5 \pm 1.1 min) than T_{∞} (4.8 \pm 1.6 min), T_{∞} (5.6 \pm 3.0 min), and T_{∞} (6.7 \pm 3.2 min). However, T_{∞} response was faster than T_{∞} (p \leq 0.001). When only T_{∞} T_{∞} and T_{∞} were compared (Table 5; n=6) the T_{∞} response (2.4 \pm 1.2 min) was faster (p \leq 0.001) than T_{∞} (5.0 \pm 2.3 min) and T_{∞} (6.7 \pm 3.3 min) responses. The response of T_{∞} was faster than the T_{∞} response (p \leq 0.001). These data indicate that T_{∞} tracked changes in core temperature faster than the other three indices. In addition, T_{∞} tracked core temperature better than T_{∞} , although T_{∞} response was not different from T_{∞} .

The slopes, △ core temperature/△ time, (n=5; Table 6) with changes in activity state (rest→moderate exercise→recovery→heavy exercise) for the four core temperature indices were greater for T_∞ (0.073±0.037°C•min⁻¹) than T_m (0.039±0.023°C•min⁻¹) and T_m (0.018±0.005°C•min⁻¹). Also, the slopes for T_m (0.049±0.029°C•min⁻¹) were greater than T_m. However, the T_m slopes were not different from T_m slopes. To evaluate an additional activity state (moderate exercise→recovery) and to include data which potentially might have an associated hysteresis, T_m T_m and T_m were compared for 5 volunteers (Table 6). T_m slopes (0.035±0.080°C•min⁻¹) were greater (p≤0.01) than T_m slopes (0.008±0.015°C•min⁻¹) and T_m slopes (0.027±0.043°C•min⁻¹) were not different from the slopes of either T_m or T_m. The comparison of the slopes of the core temperature indices also indicates that T_m responded to changes in core temperature faster than T_m and T_m.

The total change in core temperature (peak - rest; Table 7) was significantly different among the four indices (n=5; p \leq 0.01). Both T_w (0.93 \pm 0.21°C) and T_w (0.90 \pm 0.24°C) changes were greater than T_w (0.63 \pm 0.25°C) changes. The change in T_w was not different from T_w (0.76 \pm 0.25°C). When T_w T_w, and T_w were compared (n=8), the total change in core temperature was greater (p \leq 0.05) for T_w (0.99 \pm 0.18°C)

Table 5
Time (min) to Observe 0.1°C Change in Core Temperature indices
With Activity State Changes

Rest → 40% Peak Vo.

Volunteer	T.,	Tu	T _M	T,
Α	9.0	12.0	0.5	12.5
В	5.5 .	9.50	2.5	13.5
C	2.0	•	13.0	13.0
D	3.0	10.5	6.0	11.0
Ε	4.0	8.5	8.5	15.0
F	1.5	9.0	7.0	10.0
G	7.5	•	15.0	16.5
Н	3.0	•	7.5	7.0

40% Peak Vo₂ → Recovery

Volunteer	T.,	T _M	T _M	T,
A	3.0	2.5	11.0	15.0
В	3.0	4.0	3.5	11.0
C	2.0	•	3.0	15.0
D	2.5	15.0	6.5	11.0
E	2.0	11.5	10.5	15.0
F	2.0	4.5	3.5	9.0
G	2.0	•	6.5	15.0
н	2.0	•	7.5	6.5

Table 5 (cont.)

Time (min) to Observe 0.1°C Change in Core Temperature indices

With Activity State Changes

Recovery → 80% Peak Vo. (1)

Volunteer	T.,	T _u	T _M	Т"
A	2.0	5.5	4.0	5.0
В	3.5	5.0	3.0	5.0
C	1.0	•	2.5	5.0
D	1.0	10.0	4.0	5.0
E	2.0	4.0	4.0	5.0
` F	2.0	4.5	3.0	5.0
G	2.0	•	2.5	5.0
н	1.0	•	7.0	5.0

80% Peak Vo₂ (1) → Recovery

Volunteer	T.,	T _u	T _M	Т,
A	•		•	
В	5.0	0.5	5.0	5.0
C	3.0	•	5.0	5.0
D	4.0	5.0	5.0	5.0
E	2.0	5.0	5.0	5.0
F	3.5	5.0	5.0	5.0
G	2.0	•	0.5	5.0
Н	2.0	•	5.0	5.0

Table 5 (cont)

Time (min) to Observe 0.1°C Change in Core Temperature Indices

With Activity State Changes

Recovery → 80% Peak Vo. (2)

Volunteer	T.	Tu	T _M	T.,
Α	•	•	•	•
B	3.0	5.0	3.5	5.0
C	• '	•	•	•
D	2.0	5.0	5.0	5.0
E	1.5	2.5	4.0	5.0
F	0.5	5.0	3.5	5.0
G	1.5	•	2.5	5.0
H	1.5	•	5.0	5.0

80% Peak $\dot{V}C_2$ (2) \rightarrow Recovery

Volunteer	T _{••}	T _M	T _M	Т"
A	•	•	•	•
В	2.0	5.0	5.0	5.0
C	•	•	•	•
D	2.0	5.0	5.0	5.0
E	2.5	5.0	5.0	5.0
F	2.5	2.0	5.0	5.0
G	2.0	•	3.5	5.0
н	2.0	•	5.0	5.0

is the sign of the state of the

Table 5 (cont.) Time (min) to Observe 0.1°C Change in Core Temperature Indices With Activity State Changes

	Recov	rery → 80% Peak	: Vo ₂ (3)				
Volunteer	T _{ee}	T _u	T _{tet}	T.,			
A	•	•	•	•			
В	2.5	5.0	3.5	5.0			
C	•	•	•	•			
D	1.5	5.0	5.0	5.0			
E	1.5	5.0	4.5	5.0			
F 2.0	F 2.0	2.0	F 2.0 3.0	3.0	3.5	4.5	4.5
G	1.5	•	2.5	5.0			
Н	1.0	•	5.0	5.0			
	80% P	eak Vo. (3) → Re	ecovery				
Volunteer	T 	T _M	T _M	T,			
A	•	•	•	•			

Volunteer	T.,	T _u	T _M	T.,
A	•	•	•	•
В	3.0	5.0	5.0	5.0
C	•	•	•	•
D	2.0	5.0	5.0	5.0
E	2.0	5.0	5.0	5.0
F	3.0	1.5	4.0	5.0
G	2.5	•	5.0	5.0
н	2.0	•	5.0	5.0

Individual Stopes and Intercepts from Linear Regression Equations Generated From Observed Temperature as a Function of Time

Rest → 40% Peak Vo.

		Intercept	*			Stope	8	
Volumber	۴.	فيو	F ₃	L '		12	12	_ 2
<	35.56	36.46	35.89	36.42	•	0.024	0.028	
©	36.73	35.78	36.82	37.15		0.027	0.037	
ပ	36.49	•	38.14	36.39		0.054 - 0.026	0.026	0.025
۵	35.89	36.80	35.39	36.54		0.017	0.060	
ш	35.77	36.73	36.26	36.48		0.17	0.018	
Œ	35.78	36.87	36.23	36.56		0.020	0.038	
g	35.60	•	36.07	G 35.60 - 36.07 36.51	0.062	•	0.021	0.018
I	35.16	•	36.45	36.27	0.072	•	0.018	0.022

Individual Stopes and Intercepts from Linear Regression Equations Generated From Observed Temperature as a Function of Time Table 6 (cont.)

40% Peak Vo. → Recovery

		Intercept				Slope	8.	
Volunteer)_8	۳	Ļ	ب	٩	قو	13	٠٠
<	43.14				-0.069	•		
80	41.26	40.71	39.71	33.14	-0.068	-0.031	0.022	-0.310
ပ	42.81	•	39.35	38.39	-0.072	•	-0.038	-0.010
٥	37.91	•	37.75	37.75 38.25	-0.016	•	-0.00	-0.014
ш	43.34	•	37.76	•	-0.117	•	-0.016	•
u.	39.89	38.44	38.53	38.23	-0.049	-0.025	-0.020	-0.013
g	-10.91	•	38.45	37.83	-0.067	•	-0.022	-0.008
I	40.83	•	36.32	38.19	-0.069	•	-0.016	-0.015

Individual Slopes and intercepts from Linear Regression Equations Generated From Observed Temperature as a Function of Time Table 6 (cont.)

Recovery → 80% Peak Vo. (1)

		Intercept				Slope	8.	
olunteer	unteer T.	L 2	1	Τ,	_ *	قــر	卢3	۴
<	35.56	32.45	32.78	35.55	0.049	0.062	0.055	0.026
∞	30.11	31.74	34.70	35.87	0.100	0.064	0.038	0.022
ပ	28.19	•	30.34	28.19 - 30.34 -	0.121	•	0.090	•
۵	29.35	35.71	33.55	36.29	0.107	0.023	0.050	0.014
ш	27.95	32.23	33.18	35.85	0.123	0.067	0.049	0.018
u.	27.82	32.15	28.38	35.78	0.128	0.067	0.122	0.022
g	27.64	•	30,02	36.37	0.130	0.130 - 0.098	0.098	0.014
I	26.88	•	36.19	35.20	0.138	•	0.015	0.027

Individual Slopes and Intercepts from Linear Regression Equations Generated From Observed Temperature as a Function of Time Table 6 (cont.)

80% Peak Vo. (1) → Recovery

		İ	~						•
	j_2	٠	-0.013	•	•	•	•	•	-0.019
8 .	Ļ2		•	-0.054	•	-0.028	-0.054	-0.058	•
Slope	, 12		-0.044	•	•	•	-0.054	•	•
	Ļ	•	-0.035	0.090	-0.040	-0.175	-0.178	-0.125	-0.097
	- •	•	38.78	•	•	•	•	•	39.16
	F ₃		•	41.51	•	39.63	41.95	41.67	•
Intercept	Ľ		42.20	•	•	•	42.32	•	•
	F	•	40.37	44.32	40.48	50.51	51.37	46.93	44.50
	Volunteer	*	8	ပ	Q	ш	u.	g	I

Individual Slopes and Intercepts from Linear Regression Equations Generated From Observed Temperature as a Function of Time Table 6 (cont.)

Recovery → 80% Peak Vo. (2)

		Intercept	*			Š	Slope	
Volunteer	H.	F ₃	년 ,	μ.*	۳	Ľ	Ļ3	بـ و
V	•	•			•			
6	34.50	•	33.38	35.77	0.037	•	0.052	0.020
ပ	•	•	•	•	•	•	•	•
۵	32.38	•	35.82		0.061	•	0.019	•
ш	31.27	34.37	33.74	•	0.070	0.037	0.040	•
u.	27.51	35.14	30.68	•	0.121	0.028	0.085	•
g	27.87	•	31.54	•	0.115	•	0.070	•
Ĩ	29.15	•	35.73	35.46	0.096	•	0.019	0.021

Individual Stopes and Intercepts from Linear Regression Equations Generated From Observed Temperature as a Function of Time Table 6 (cont.)

Recovery → 80% Peak Vo. (3)

	۳		•		•	•	•	•	•
2	1 2		0.052	•	0.024	0.029	0.044	0.158	•
Slope	۲3	•	•	•	•	0.039	0.037	•	•
	Ļ3		0.101	•	0.058	0.075	0.077	0.163	0.145
	Ļ*		•	•	•	•	•	•	
~	1 2	•	32.98	•	35.29	34.47	33.88	22.73	•
Intercept	1		•	•	•	33.97	3.8	•	•
	T.	•	28.17	•	32.02	30.23	30.41	22.35	23.69
	Volunteer	∢	80	ပ	٥	ш	L.	Ø	I

Table 7
Change in Core Temperature (°C) from Rest Temperature to Peak Temperature

Volunteer	T.	T _M	T _M	T,
Α	1.15	0.61	2.90	0.97
В	0.63	0.26	0.65	0.36
С	1.04	•	0.54	0.74
D	0.96	0.61	1.16	0.83
E	0.82	0.70	0.68	0.68
F	1.07	0.95	1.12	0.97
G	1.24	•	1.24	0.73
Н	1.04	•	0.96	0.96

than T_m (0.78±0.19°C). The total change in T_m (0.91±0.24°C) was not different from T_m or T_m . The sluggish response of T_m and T_m was probably part of the reason for these differences, but the total change in T_m was an average of 0.36°C lower than T_m ; perhaps the KI sensors are not as effective as thermocouples. On the other hand, the other choice for monitoring core temperature in field studies is T_m and the total change in T_m was not significantly different from T_m . The poor showing of the T_m was not inherent to a temperature sensor/pill per se, as the change in T_m was not different from T_m .

 T_m , as an index of core temperature, is useful when an individual is in thermal equilibrium (7, 8, 11, 15, 16) and data from the current study indicate that T_m lags behind T_m by 12-25 min (Tables 3-6). Even though the moderate exercise period was 40 min (rest—moderate exercise; Table 3), T_m was not always equilibrated by the end (Figures 6,12,14,16). However, the mean change in core temperature during moderate exercise was measured as effectively by T_m as any other core temperature index (Table 4). On the other hand, Table 4 also shows that T_m response during rapid changes in core temperature was often changing opposite to T_m . During heavy exercise in a hot environment, a delay in detecting a substantial increase in core temperature might contribute to heat injury.

The primary purpose of this study was to evaluate whether or not the temperature pill telemetry systems were reliable and accurate indices of core temperature. The evaluation of the KI system (CDUSS, BSMS and BFMS) was of special interest because its development had been funded, in part by the US Army (P²NBC² program) with the intention to use the KI system as a clinical index of core temperature to prevent heat injury in field studies (12, 18, 19). Specifications of this system predict that core temperature can be transmitted for 150 meters, or up to two km if a relay system is used (18). However, the KI telemetry system used in the current study could not transmit even one meter in USARIEM, so the relay portion of the telemetry was not used in this study. The data collected with the prototype KI system were unreliable to the extent that substantial data were lost. Some statistical analysis were possible, although the small volunteer number (n=5) limited the interpretation to the population used in the study. Not only was the prototype KI telemetry system unreliable in the current study, the KI pill as a temperature sensor was inaccurate as shown by the extensive water bath calibration data for two KI pills (Figure 17). For example, for a water bath temperature of 38.05-

38.08°C, the temperature of KI Pill #70 ranged between 35.45-37.75°C. The temperature of KI Pill #121 ranged between 36.05-37.59°C for a water bath temperature of 38.05-38.08°C. If the KI pill is this inaccurate in a water bath calibration, when the sensors equilibrated for 8.5 min as data were collected, it may not be suitable for use as a clinical index of core temperature. Rigorous bench tests of the KI sensor should be made to determine the nature of its response to changing water bath temperature to discount the possibility that the data shown in Figure 17 are representative of all KI pills. These bench tests should be conducted before the KI sensor is used as a clinical thermometer.

Equilibrated T_w, during rest and moderate exercise, was similar to T_m. There were also some outliers in the Tu data as shown in the figures, but the bigger problem in the KI system was an inability to detect the KI pill signal. Peak Tw was not different from any These observations indicate that T_m of the other core temperature indices. (37.79±0.11°C) was as effective as T_m (37.75±0.14°C) when used to measure the peak temperature during the heavy exercise/rest cycles (Table 3). Further, T_u (0.63±0.25°C) was as effective an index as T_m (0.76±0.25°C) when used to measure the change in core temperature from rest to peak, although the change in T_x was significantly less (p≤0.01; Table 7) than T_→ (0.93±0.21°C) and T_→ (0.90±0.24°C). When the quickness of response of T_w was evaluated (Tables 4, 5 and 6), the average time it took for T_w to reach an equilibrated temperature during moderate exercise was 18 min faster than for T, to reach an equilibrated temperature. During heavy exercise the time it took T_x to reach the highest temperature during the exercise or recovery period was not different than any other index. This was mainly because the time was constrained to the five min periods and the temperatures were not necessarily equilibrated (Figures 1-8).

The change in T_{u} with change in activity state was greater than the change in T_{w} (n=4; 3 activity states; Table 4), while the change in T_{u} was less than T_{w} (n=4; 8 activity states). Although T_{w} changed more during changes in activity state than T_{u} , the change in T_{u} was greater than T_{w} . The time it took for a 0.1°C change in T_{u} was about the same as the time it took T_{w} , and it was about three min slower than T_{w} (p≤0.001; Table 5). The slope changes with activity state changes were much less for T_{u} compared to T_{w} (Table 6), but T_{u} slopes were not different from the slopes of T_{w} . The weight of the data for T_{u} response indicates that it is not as fast as T_{w} , but just as quickly responding as T_{w} . Although the absolute peak temperature of T_{u} was not different from T_{w} . T_{w} or T_{w} during heavy

exercise, the total change in T_u (0.63°C±0.20) was significantly less (p≤0.01; Table 7) than in T_∞ (0.99±0.18°C) and T_M (0.91±0.19°C). T_M during a 1.0°C change in core temperature, lagged by nearly 0.4°C. Therefore, T_M did not measure large changes in core temperature as effectively as T_∞ or T_M. Part of the lag in T_M might be due to an apparent inconsistency in the response characteristics of the KI pill. In the Appendix, Figure 17 (KI pill #70 and KI pill #121) shows extensive calibration data (> 3 h). There was a large and obvious hysteresis for both KI pill #70 (Volunteer A) and KI pill #121 (Volunteer B). The hysteresis may or may not explain the smaller total change in T_M compared to T_M.

T_m could be compared to T_m and T_m more extensively than could be done with the KI telemetry system because fewer data were lost with the HTI telemetry systems. There were sporadic outlying points in T_m data as can be seen from the figures of the individual data, as occurred with Tu data. Table 3 shows that the steady state rest Tn was not different from T, but was 0.2 and 0.26°C lower than T, and T, respectively. During moderate exercise, T_m was not different from T_m or T_m but averaged 0.26°C lower than T... The difference between T. and T. averaged 0.2°C and 0.3°C at rest and during moderate exercise, respectively. The only published report (24) comparing T_m with T_m indicated that the difference between T_m and T_m for rest and exercise was about 0.4°C and 0.8°C, respectively. The differences between the two temperatures were much greater as reported by Sparling *et al.* (24) than in the cuπent study, but that may be due to experimental design, variation in pill mobility, whether there was water in the gut, or whether a small meal was eaten after pill ingestion. Figure 7 shows that T_™ was abnormally low during moderate exercise, presumably because there was water in the gut. Later in the experiment T_™ response improved markedly, presumably because the HTI pill moved out of the stomach. Also, in one volunteer (B), Tm was greater than Tm throughout the experiment (Figure 2). In this study, peak Tm was not different than the other three core temperature indices during heavy exercise. However, the total change in T_m averaged 0.28°C greater than T_m and was not significantly different from T_m and T_m (Table 7). The HTI pill detected the total change in core temperature better than the KI pill (p≤0.01). This difference between the two pills might be due to the hysteresis detected during calibration of the KI pills (Figure 17). The HTI calibration data are presented in Figures 13-16. A heated water bath interfered with HTI signal transmission. Consequently, the calibration was done only on decreasing water temperature without

checking for hysteresis, but the correlation coefficients for the HTI pill calibration were much better than those for the KI pill calibrations (Figures 9-12). During moderate exercise (Table 3) T equilibrated 12 min faster than T, although T, equilibrated about 7 min faster than T_m. During heavy exercise, the time at which the peak T_m occurred was not different from the time of peak T or T. During changes in activity state, the change in T was greater than the change in T, but less than the change in T. The time of an observable change (0.1°C) in core temperature with a change in activity state (Table 5) for T_m was 2-3 min faster than T_m, but 2-2.5 min slower than T_m (p≤0.001). Using this method of analysis, Tm tracked core temperature better than Tm while Tm was not different from T_n. In the slope analysis from two changes in activity state indicated that T_m slopes were greater than T, but not different from T,. By contrast, the T, slopes were not different from T, slopes, but less than T, slopes (Table 6). Again, by using this analysis, Tw was a more responsive index of core temperature than Tw, yet Tw responded as did T,. Overall, these analyses indicated that T, tracked rapid changes in core temperature significantly faster than T, although T, did not track dynamic changes as well or as consistently as did T... T. was an effective index of the total change in core temperature (~1°C) during the experiment (Table 7).

CONCLUSIONS

In our hands, $T_{\tt u}$ was not reliable due to many problems, as detailed in the METHODS. The KI sensor itself, when calibrated extensively in a water bath, was inaccurate. When the prototype KI telemetry system was functioning, we obtained limited data (n=5) pertaining to the use of $T_{\tt u}$ as an index of core temperature. In some cases, $T_{\tt u}$ responded better to dynamic changes in core temperature than $T_{\tt u}$, but $T_{\tt w}$ was undeniably more reliable than $T_{\tt u}$. $T_{\tt w}$ was a better index of core temperature than $T_{\tt u}$ in that it was more reliable, more responsive and more accurate.

The reliability of the HTI telemetry system as a data acquisition system was far better than the prototype KI telemetry system. However, screening, by water bath calibration, was still required to ensure that the HTI sensor measured temperature accurately. As a core temperature index, $T_{\rm ht}$, for the most part was accurate with some drawbacks: 1) mobility of the pill in the GI tract caused changes in insulation and absolute temperature and made $T_{\rm ht}$ less reliable than $T_{\rm ht}$ and $T_{\rm ht}$ and 2) the response characteristics of the HTI pill did change several times which is probably related to pill mobility or water in the GI tract.

The concept of using a temperature sensor in a pill (26) may be useful clinically, but mobility of the pill makes this temperature measurement less suitable for research than esophageal or rectal temperature measurements. If new evidence indicates the KI pills are reliable and accurate, further testing should be initiated to test the KI telemetry system when used in conjunction with the KI pills before the KI telemetry system is used as a clinical index of core temperature. Field use of T_M would still require a medical observer in close proximity to the soldiers since the pill transmits a signal to a receiver worn on the body and is not relayed further by telemetry. However, the HTI system is equipped with an audio alarm that may be activated when safe temperature limits have been exceeded.

RECOMMENDATIONS

Before the KI pill is used as a clinical thermometer, it is recommended that the KI temperature sensors be rigorously tested in a bench test to determine the nature of the KI pill response to changing water bath temperature (as measured by a thermometer calibrated to National Bureau of Standards specification). The bath temperature should be changed as fast as the human body can store heat during vigorous exercise (~0.6°C in 5 min at 80% peak $\dot{V}o_2$). Finally, the bench test should include both increasing and decreasing water bath temperatures over the range of human core temperature.

Due to the high failure rates observed during water bath calibrations of both the HTI and KI pills, it is recommended that a suitable water bath calibration be done on each pill by the investigator within a day or two of human ingestion.

Temperature pills should not be used for research from which decisions will be made regarding heat storage differences between different uniforms, uniform/systems, microclimate cooling, and other personal equipment for the soldier such as sleeping bags. This recommendation is based on the variable and sometimes sluggish pill temperature responses due to the changing anatomical location of the pill during these 100 min experiments. A change of 0.2-0.3°C due to changing pill location could confound findings.

In this study the HTI telemetry system was tested in the laboratory and the instrument was protected from excessive wear as much as necessary. Under field conditions, additional precautions to protect the HTI data logger might be necessary. The HTI telemetry system has been tested under field conditions recently (4) and found to operate successfully in extreme environments.

REFERENCES

- 1. Baker, M. A., R. A. Stocking, and J. P. Meehan. Thermal relationship between tympanic membrane and hypothalamus in conscious cat and monkey. *J. Appl. Physiol.*32: 739-742, 1972.
- 2. Brengelmann, G. L. Dilemma of body temperature measurement. In:Man in Stressful Environments. Thermal and Work Physiology. edited by K. Shiraki, and M. K. Yousef. Springfield, IL: Charles C. Thomas, 1987, p. 5-22.
- 3. Brinnel, H., and M. Cabanac. Tympanic temperature is a core temperature in humans. *J. Therm. Biol.*14:47-53, 1989.
- 4. Bruckart, J. E., J. R. Licina, B. Olding, and M. Quattlebaum. Test and evaluation report of the Human Technology Ambulatory Cortemp Recorder Model COR-124. USAARL Report No. 92-19, March, 1992, Fort Rucker, Alabama 36362-5292.
- 5. Cabanac, M. Keeping a cool head. News Physiol. Sci.1:41-44, 1986.
- 6. Cabanac, M., and M. Caputa. Natural selective cooling of the human brain: evidence of its occurrence and magnitude. *J. Physiol. (Lond.)* 286:255-264, 1979.
- 7. Eichna, L. W., A. R. Berger, B. Rader, and W. H. Becker. Comparison of intracardiac and intravascular temperatures with rectal temperatures in man. *J. Clin. Invest.* 30:353-359, 1951.
- 8. Gerbrandy, J., E. S. Snell, and W. I. Cranston. Oral, rectal and oesophageal temperatures in relation to central temperature control in man. *Clin. Sci.* 13:615-624, 1954.
- 9. Greenleaf, J. E., and B. L. Castle. External auditory canal temperature as an estimate of core temperature. *J. Appl. Physiol.* 32: 194-198, 1972.

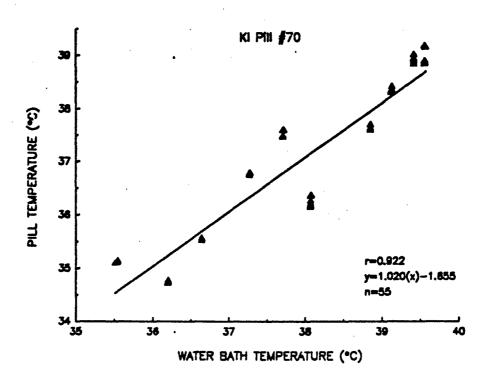
- 10. Jessen, C., and G. Kuhnen. No evidence for brain stem cooling during face fanning in humans. J. Appl. Physiol. 72: 664-669, 1992.
- 11. Kolka, M. A., L. A. Stephenson, S. P. Bruttig, B. S. Cadarotte, and R. R. Gonzalez. Human thermoregulation after atropine and/or pralidoxime administration. *Aviat. Space Environ. Med.* 58: 545-549, 1987.
- 12. Konigsberg, E. Dispersed telemetry system for measurement of body temperatures. Final Report to Naval Supply Systems Command and Navy Clothing and Textiles March, 1990.
- 13. Mackay, R. S. Bio-Medical Telemetry. Second Ed., New York: John Wiley & Sons, Inc., 1970, p. 154-159.
- 14. Mead, J., and C. L. Bonmarito. Reliability of rectal temperatures as an index of internal body temperature. *J. Appl. Physiol.* 2:97-109, 1949.
- 15. Mittleman, K. D., and I. B. Mekjavic. Effect of occluded venous return on core temperature during cold water immersion. *J. Appl. Physiol.* 65:2709-2713, 1988.
- 16. Molnar, G. W., and R. C. Read. Studies during open-heart surgery on the special characteristics of rectal temperature. *J. Appl. Physiol.* 36:333-336, 1974.
- 17. Nadel, E. R. Comments on "Keeping a cool head" by M. Cabanac. News Physiol. Sci. 2: 33, 1987.
- 18. Redmond, D., J. R. Leu, K. A. Popp, G. W. Hall, C. Galinski, and P. E. Gutierrez. Medical monitoring: Assessment of physiological changes in military personnel during field studies. In: Banderet et al. Proceedings of a symposium—Consequence of wearing the chemical protective ensemble: illustrative assessment approaches. U.S. Army Research Institute of Environmental Medicine Technical Note 9-92, Natick, Massachusetts March, 1992 p. 31-40.
- 19. Redmond, D. P., J. R. Leu, K. A. Popp, P. E. Gutierrez, Jr., and S. W. Hall, Jr.

- The Walter Reed temperature pill: Evaluations for clinical and investigational usage. WRAIR Technical Report Aug, 1990.
- 20. Rowell, L. B. Cardiovascular adjustments to thermal stress. In: <u>Handbook of Physiology-The Cardiovascular System III</u>, edited by J. T. Shepherd, and F. M. Abboud. Bethesda: Am. Physiol. Soc., 1983, Chapter 27, p.967-1023.
- 21. Sharkey, A., P. Elliott, J. M. Lipton, and A. H. Giesecke. The temperature of the air within the external auditory meatus compared with esophageal temperature during anaesthesia and surgery. *J. Therm. Biol.* 12: 11-13, 1987.
- 22. Shiraki, K., N. Konda, and S. Sagawa. Esophageal and tympanic temperature responses to core blood temperature changes during hyperthermia. *J. Appl. Physiol.* 61:98-102, 1986.
- 23. Shiraki, K., S. Sagawa, F. Tajima, A. Yokota, M. Hashimoto, and G. L. Brengelmann. Independence of brain and tympanic temperatures in an unanesthetized human. *J. Appl. Physiol.* 65: 482-486, 1988.
- 24. Sparling, P. B., T. K. Snow, and M. Millard-Stafford. Monitoring core temperature during exercise: ingestible sensor vs rectal thermistor (abstract). *Med. Sci. Sports Exerc.* 24:S153, 1992.
- 25. Wenger, C. B. More comments on "Keeping a cool head" by M. Cabanac. *News Physiol. Sci.* 2: 150, 1987.
- 26. Wolff, H. S. The radio pill. New Scientist 16:419-421, 1961.

APPENDIX CALIBRATIONS

Table 8. Telemetry Pill Identification and Calibration Correlation Coefficients for Esophageal and Rectal Temperatures

Volunteer	KI Pill #	HTI Pili #	T _{ee} Calibration (r)	T., Calibration (r)
A	70	901439	1.00	0.999
В	121	904310	0.990	0.990
С	140	901444	0.990	0.988
D	159	901426	0.990	0.989
Ε	48	904809	0.990	0.988
F	75	904817	0.990	0.989
G	204	904751	0.990	0.988
н	None	904753	0.990	0.989



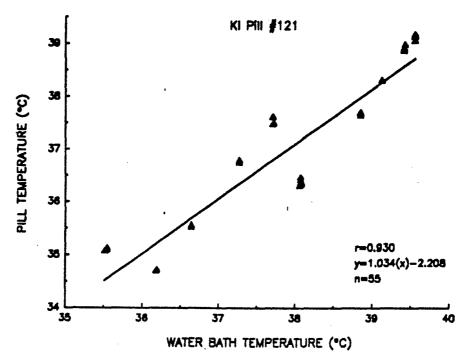
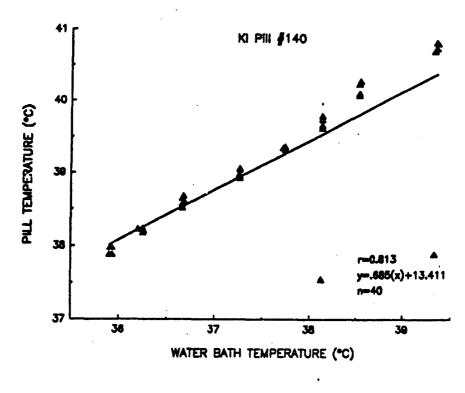


Figure 9 Correlation coefficients for KI pills ingested by Volunteers A and B.



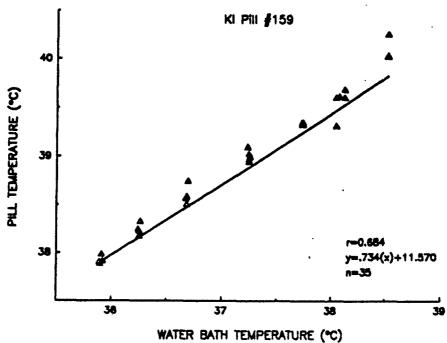
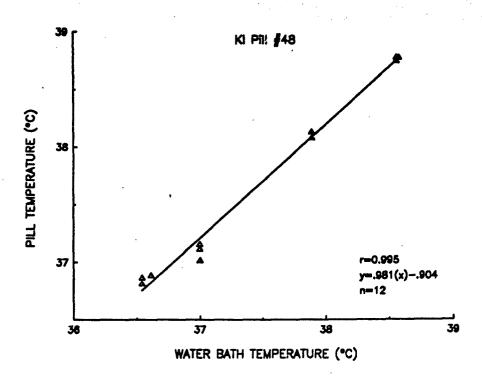


Figure 10 Correlation coefficients for KI pills ingested by Volunteers C and D.



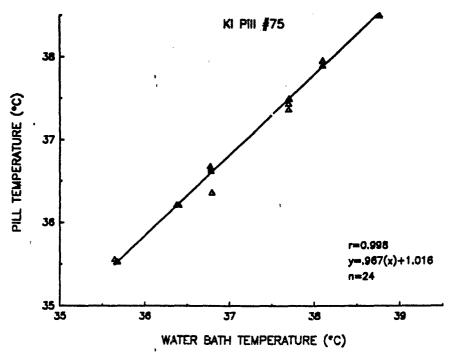


Figure 11 Correlation coefficients for KI pills ingested by Volunteers E and F. 65

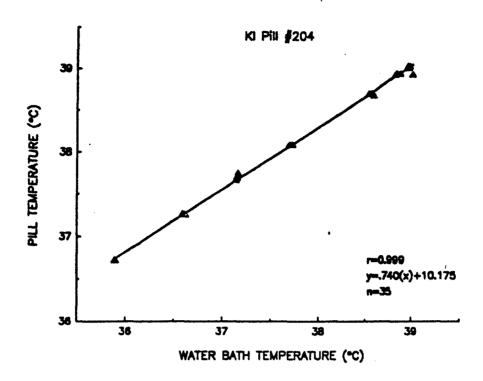


Figure 12 Correlation coefficients for KI pill ingested by Volunteer G.

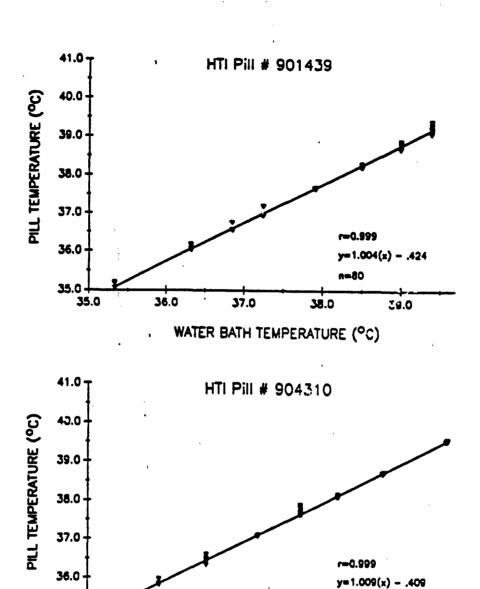


Figure 13 Correlation coefficients for HTI pills ingested by Volunteers A and B.

36.0

35.0 + 35.0

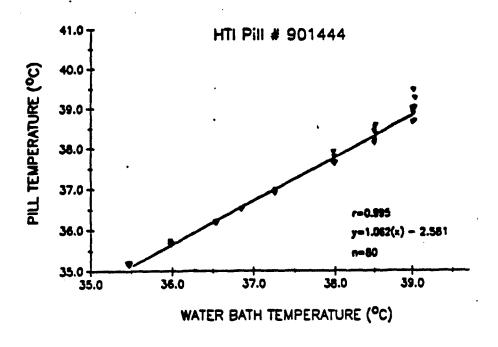
37.0

WATER BATH TEMPERATURE (°C)

n=80

39.0

38.0



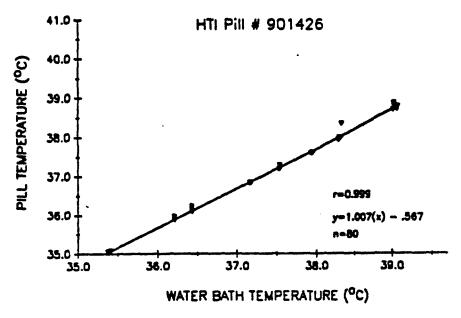
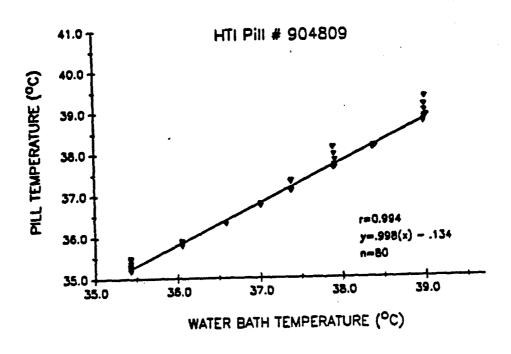


Figure 14 Correlation coefficients for HTI pills ingested by Volunteers C and D.



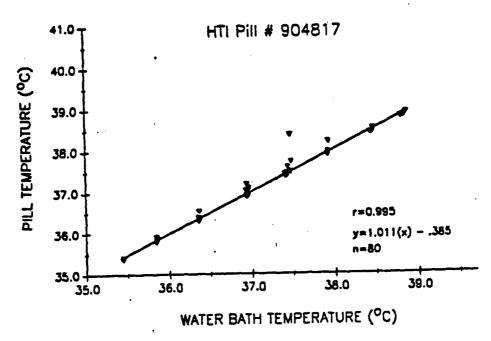
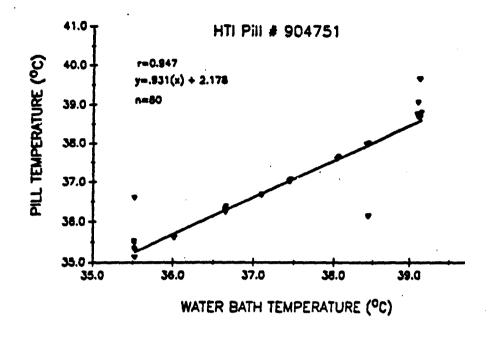


Figure 15 Correlation coefficients for HTI pills ingested by Volunteers E and F.



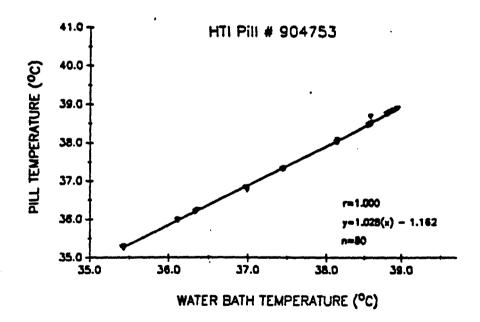
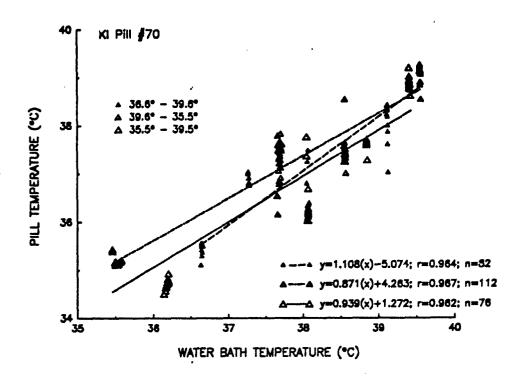


Figure 16 Correlation coefficients for HTI pills ingested by Volunteers G and H.



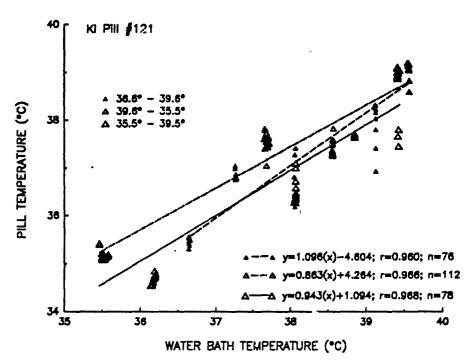


Figure 17 Hysteresis seen during calibration of KI pills ingested by Volunteers A and B.

DISTRIBUTION LIST

4 Copies:

Defense Technical Information Center

ATTN: DTIC-DDA

Alexandria, VA 22304-6145

2 Copies to:

Commander

U.S. Army Medical Research and Development Command

ATTN: SGRD-OP

Fort Detrick

Frederick, MD 21701-5012

Commander

U.S. Army Medical Research and Development Command

ATTN: SGRD-PLE

Fort Detrick

Frederick, MD 20701-5012

Commander

U.S. Army Medical Research and Development Command

ATTN: SGRD-PLC

Fort Detrick

Frederick, MD 20701-5012

Commandant

Academy of Health Sciences, U.S. Army

ATTN: AHS-COM

Fort Sam Houston, TX 78234-6100

Commander

U.S. Army Medical Research Institute of Chemical Defense Aberdeen Proving Ground, MD 21010-5425

Commander

U.S. Army Chemical Research, Development and Engineering Center ATTN: Mr. Blewett
Aberdeen Proving Ground, MD 21010-5423

Commandant

U.S. Army Chemical School Fort McClellan, AL 36205-5020

20. TARREST AND A CONTRACT OF THE PARTY OF

Commander

Armstrong Laboratory
Brooks Air Force Base, TX 78235-5000

Commander

U.S. Air Force School of Aerospace Medicine Brooks Air Force Base, TX 78235-5000

Commander

U. S. Army Human Engineering Laboratory Aberdeen Proving Ground, MD 21005-5001

Commanding Officer
Naval Health Research Center
P.O. Box 85122
San Diego, CA 92138-9174

Commander

U.S. Army Biomedical Research and Development Laboratory
Fort Detrick
Frederick, MD 21701-5010

Commander
U.S. Army Medical Materiel Development Activity
Fort Detrick
Frederick, MD 21701-5009

Defence and Civil Institute of Environmental Medicine
1133 Sheppard Avenue W.
P.O. Box 2000
Downsview, Ontario
CANADA M3M 3B9

1 Copy to:

Stimson Library
Academy of Health Sciences, U.S. Army
ATTN: Chief Librarian
Bidg. 2840, Room 106
Fort Sam Houston, TX 78234-6100

Director, Biological Sciences Division Office of Navai Research - Code 141 800 N. Quincy Street Arlington, VA 22217

Commanding Officer
Naval Medical Research and Development Command
NMC-NMR/ Bldg. 1
Bethesda, MD 20814-5044

Office of Undersecretary of Defense (Acquisition)
ATTN: Director, Defense Research and Engineering
(Environmental and Life Sciences)
Pentagon, Rm. 3D129
Washington D.C. 20301-3080

Dean

School of Medicine
Uniformed Services University Of The Health Sciences
4301 Jones Bridge Road
Bethesda, MD 20814-4799

Director

Walter Reed Army Institute of Research
Walter Reed Army Medical Center
ATTN: SGRD-UWZ-C (Director for Research Management)
Washington D.C. 20307-5100

Director

Waiter Reed Army Institute of Research ATTN: SGRD-UWI-C (COL D. Redmond) Washington D.C. 20307-5100

Commander

U.S. Army Environmental Hygiene Agency Aberdeen Proving Ground, MD 21010-5422

Commander

U.S. Army Military History Institute
Carlisle Barracks
ATTN: Chief, Historical Reference Branch
Carlisle, Pennsylvania 17013-5008

Commandent

U. S. Army Chemical School ATTN: ATZN-CM-CT (Mr. Cunningham) Fort McClellan, AL 36205-5020 Commandant
U. S. Army Chemical School
ATTN: ATZN-CM-CT (Mr. Creech)
Fort McClellan, AL 36205-5020

10 Copies to:

Commandant
Academy of Health Sciences
ATTN: HSHA-FR (USAMRD Liaison Officer)
Fort Sam Houston, Texas 78234-6100

Scientific Information Center
U. S. Army Aeromedical Research Laboratory
Fort Rucker, AL 36362-5292